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Annual dialysis data report 2020, JSDT renal data registry



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Abstract

Background The 2020 Japanese Society for Dialysis Therapy Renal Data Registry (JRDR) annual survey was sent to 4493 dialysis facilities in Japan.

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

Results In total, 4437 facilities (98.8%) responded to the facility questionnaire and 4271 (95.1%) responded to the patient questionnaire. The number of chronic dialysis patients in Japan continues to increase every year, reaching 347,671 at the end of 2020 and giving a prevalence rate of 2754 patients per million population. The mean age was 69.40 years. Diabetic nephropathy was the most common primary disease among the prevalent dialysis patients (39.5%), followed by chronic glomerulonephritis (25.3%) and nephrosclerosis (12.1%). There were 40,744 incident dialysis patients during 2020, representing a decrease of 141 from 2019. The average age of patients on dialysis was 70.88 years, with diabetic nephropathy being the most common underlying disease (40.7%) second most common was nephrosclerosis (17.5%), which was unchanged from the previous year and surpassed chronic glomerulonephritis (15.0%). There were 34,414 patient deaths in 2020; the crude mortality rate was 9.9%. The main causes of death were heart failure (22.4%), infection (21.5%), and malignancy (9.0%), which were almost the same as the percentages for the previous year. Since 2012, the number of patients treated by hemodiafiltration has increased rapidly; in 2020, the number of patients on this modality was 163,825, accounting for 47.1% of all patients on maintenance dialysis. The number of patients on peritoneal dialysis has been on the rise since 2017, reaching 10,338 in 2020; 20.8% of whom received combined therapy with hemodialysis or hemodiafiltration, showing no change from the previous year. A total of 751 patients were on home hemodialysis at the end of 2020, representing a decrease of 9 from the end of 2018. In 2020, coronavirus disease 2019 (COVID-19) infection and malignancy were added as new items in the survey. Continuing on from the 2019 survey, history of kidney donation for a living-donor transplant was investigated.

Conclusions Present issues and challenges in renal replacement therapy were identified in the responses to the new questionnaire items included in this survey. A more detailed evaluation with adjustment for patient background factors should clarify the characteristics of the underlying diseases and conditions in dialysis patients.

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Trial registration The JRDR was approved by the Japanese Society for Dialysis Therapy ethics committee. It was registered in the University Hospital Medical Information Network (UMIN) Clinical Trials Registry on 10 September 2020 and in the UMIN clinical trials registration system (UMIN000018641).

Keywords COVID-19, Hemodialysis, Hemodiafiltration, Kidney transplantation, Malignant tumor, Peritoneal dialysis

Part I 2020 JRDR annual data report: general remarks

Introduction

Since 1968, the Japanese Society for Dialysis Therapy (JSDT) has performed annual surveys of the status of maintenance dialysis in Japan. The data collected are entered into the JSDT Renal Data Registry (JRDR). This survey encompasses nearly all dialysis centers in Japan [1, 2], and most facilities take part despite participation being voluntary. Owing to the comprehensive nature of the survey, the data obtained accurately reflect the current status of maintenance dialysis in Japan.

Since 2017, the JRDR annual report has been published as a full-color article in the December issue of the *Journal of the Japanese Society for Dialysis Therapy*. The illustrated edition of the annual report has been discontinued. The JSDT has created the web-based analysis of dialysis data archives (WADDA) system, which enables users to specify their own conditions for tabulating data on the web [3].

The WADDA system has significantly improved the usability of the JRDR survey results for JSDT members and enables them to perform cross-sectional analyses of the most recent data. In 2019, the society ceased distributing the CD-ROM edition of "An Overview of Regular Dialysis Therapy in Japan" to its members. Since then, we have encouraged society members to use the WADDA system.

Malignancy and coronavirus disease 2019 (COVID-19) were included in the survey for the first time in 2020. The history of renal donation for living-donor transplantation was also investigated in 2019. This survey will provide health care professionals managing dialysis patients with a deeper understanding of each condition, allowing them to optimize the daily clinical practice of dialysis therapy.

Ethical basis for the JRDR survey

The annual JRDR survey is conducted in accordance with the "Ethical Guidelines for Medical and Health Research Involving Human Subjects" issued in December 2014 and revised in February 2017 by the Ministry of Health, Labour and Welfare and the Ministry of Education, Culture, Sports, Science and Technology. In March 2015, the JSDT ethics committee approved the basic strategy for the annual survey and ensured compliance with the Act on the Protection of Personal Information (approval number 1). The modifications made to the basic plan for the 2020 survey were approved by the JSDT ethics committee on 10 September 2020 and entered in the University Hospital Medical Information Network (UMIN) clinical trial registration system (UMIN000018641).

Survey methods

1. Distribution and collection of survey forms

The JRDR survey includes two questionnaires. The first is a facility questionnaire, which collects information on the number of dialysis beds, patients, and measures in place to control the quality of dialysis fluid. The second is a patient questionnaire, which collects data on dialysis conditions, laboratory findings, and outcomes for each individual patient at any given dialysis facility. In December 2020, a USB flash drive containing a password-encrypted Excel-based facility survey and the anonymized 2019 patient survey was sent to all dialysis centers across Japan. Each dialysis center utilized the USB flash drive containing the anonymizing table provided in 2015 to retrieve actual names and then updated the laboratory data and outcomes, including deaths, transplants, and transfers. After enrolling new patients and updating the existing patient data in the questionnaire, the data were re-anonymized using the USB flash drive containing the anonymizing table. Each dialysis center then sent only the USB flash drive containing the responses to the questionnaire to the secretariat of the JSDT after ensuring that patients' personal information had been totally anonymized. The initial deadline for data collection was 15 February 2021. Facilities that did not return their data by this date were reminded to do so, with the final deadline set as 19 June 2021.

2. Survey items

The following items were surveyed in 2020.

I. Facility survey

1. Overview and size of facility

Facility code, facility name, and date of initiation of dialysis (in years and months)

Dialysis capacity: number of dialysis machines, number of patients that can be treated at the same time, maximum number of treatable patients, number of dialysis machines equipped with an endotoxin-retentive filter, and number of dialysis staff members

2. Patient dynamics

Number of dialysis patients at the end of 2020 (by treatment method and whether treatment was provided on an inpatient or outpatient basis)

Number of patients on nocturnal dialysis in 2020

Number of incident patients [i.e., started on hemodialysis (HD), hemodiafiltration (HDF), or peritoneal dialysis (PD)] in 2020

Number of patients who died in 2020

3. Quality control status for dialysis fluid

Frequency of measurement of endotoxin level in dialysis fluid and results

Frequency of measurement of total viable microbial count (TVC) in dialysis fluid and results

Source of water supply for dialysis fluid

Method used for measurement of residual chlorine and frequency of measurement

Awareness of water quality standards for chemical contaminants issued by the JSDT and frequency of measurement

II. Patient survey

1. Patient demographics

Sex, date of birth, year of initiation of dialysis, primary disease, prefecture of residence, year of transfer, code of facility before 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, whether HD/HDF was added to PD, experience of PD, number of previous kidney transplants, history of kidney donation, year of kidney donation, and presence of malignancy and its type at the end of 2020.

2. Treatment conditions for HD/HDF

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

Dilution method and volume of replacement fluid per HDF session.

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

3. Laboratory data

Blood urea nitrogen and serum creatinine levels measured before and after dialysis; serum albumin, C-reactive protein, calcium, phosphorus, parathyroid hormone, total cholesterol, and serum high-density lipoprotein cholesterol levels and hemoglobin measured before dialysis sessions; tests for COVID-19 and month of first positive result for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), if applicable.

4. Outcomes

Use of antihypertensive medication, smoking status, and history of diabetes, ischemic heart disease, cerebral hemorrhage, cerebral infarction, limb amputation, hip fracture, and encapsulating peritoneal sclerosis.

5. Survey of PD

Treatment history: total duration on PD and months on PD in 2020.

Peritoneal function: results of the peritoneal equilibrium test and ratio of creatinine concentration in dialysate to that in plasma 4 h later.

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

Dialysis modality: automated PD, PD dialysate exchange.

PD-related infections: annual numbers of episodes of peritonitis and exit site infections.

3. Number of facilities that responded to the survey

The 2020 survey was distributed to 4493 facilities nationwide in Japan. The facility questionnaire was answered by 4437 facilities (98.8%). In comparison with the previous year, 26 additional facilities (an increase of 0.6%) answered the facility survey. The JSDT office received responses to the patient survey from 4271 facilities (95.1%).

Part II Results of the 2020 JSDT statistical survey report and discussion

Chapter 1. Status of chronic dialysis therapy in 2020 in Japan

1. Facility dynamics

The 2020 survey included 4493 facilities nationwide. The response rate showed a transient decline in 2015.

Table 1 Summary of chronic dialysis therapy in Japan, 2020

| (a) Numb | per of facilities and dialysis capa | city | | | | | |
|-------------|--------------------------------------|---------------|--------|------------|--------|--------------------|-------------------------|
| Number | of facilities and dialysis capacity | 1 | | Number | | Cha prev (%) | nges from vious year |
| Surveyed | facilities | | | 4493 | | +6 (| +0.1) |
| Respondi | ng facilities | | | 4437 | | +26 | (+0.6) |
| Dialysis ca | apacity | | | | | | |
| Number o | of bedside machines | | | 143,772 | | +22 | .52 (+1.6) |
| Capacity | for simultaneous HD treatments | | | 141,752 | | +19 | 13 (+1.4) |
| Maximum | n patient capacity | | | 472,531 | | +79 | 16 (+1.7) |
| (b) Patier | nt dynamics | | | | | | |
| Patient c | ategory | | Num | ber | | Cha prev (%) | nges from vious year |
| Prevalent | patients | | 347,6 | 571 | | +30 | 31 (+0.9) |
| Prevale | ence rate (per million of general po | opulation) | 2754 | .3 | | +22 | 7 |
| Patient | s on nocturnal dialysis | | 31,46 | 8 | | -55 | 9 |
| Incident p | patients | | 40,74 | 14 | | -14 | 1 (-0.3) |
| Startec | on HD or HDF | | 38,26 | 53 | | | |
| Startec | on PD | | 2481 | | | | |
| Deceased | patients | | 34,41 | 4 | | -22 | 8 (-0.7) |
| (c) Numb | ers of prevalent dialysis patient | s by modality | | | | | |
| Modality | | Outpatients | s (%) | Inpatients | (%) | Total (%) | |
| HD | HD | 149,082 | (47.0) | 22,242 | (72.5) | 171,324 | (49.3) |
| | HDF | 155,782 | (49.0) | 8,043 | (26.2) | 163,825 | (47.1) |
| | HF | 10 | (0.0) | 4 | (0.0) | 14 | (0.0) |
| | HAD | 1369 | (0.4) | 50 | (0.2) | 1419 | (0.4) |
| | Home HD | 750 | (0.2) | 1 | (0.0) | 751 | (0.2) |
| PD | PD only | 7916 | (2.5) | 272 | (0.9) | 8188 | (2.4) |
| | PD+HD 1×/week | 1839 | (0.6) | 43 | (0.1) | 1882 | (0.5) |

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

(0.1)

(0.0)

(0.0)

(100.0)

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1

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30.667

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

161

30

65

317,004

HAD refers to hemodialysis therapy combined with hemoadsorption using a tandem-connected beta-2 microglobulin adsorptive column

In 2020, the response rate was 98.8%, which was almost the same as in previous years, with responses received from a further 26 facilities (an increase of 0.6%) in comparison with 2019 (Table 1). The patient survey was completed by 4271 facilities, giving a response rate of 95.1%. The patient survey response rate has decreased from around 96% to about 95% since the 2015 survey. The need for further anonymization and cessation of paper-based surveys in 2015 may have contributed to

PD+HD 2×/week

PD+HD 3x/week

Total

PD+HD other frequencies

this decline. However, the rate has remained at around 95%. The number of dialysis machines, number of patients who could be dialyzed simultaneously, and maximum capacity were 143,772, 141,752, and 472,531, respectively, representing increases of 1.6%, 1.4%, and 1.7% in comparison with the numbers recorded at the end of 2019 (Table 1). The number of dialysis machines available has increased year by year (Additional file 1: Table S1).

(0.0)

(0.0)

(0.0)

(100.0)

165

31

72

347,671

(0.0)

(0.0)

(0.0)

(100.0)



Fig. 1 Trends in the number of prevalent dialysis patients, 1968–2020, and the adjusted rate of prevalent dialysis patients (per million population), 1983–2020. pmp, per million population

2. Patient demographics

According to the results of the facility survey, 347,671 patients were receiving chronic dialysis therapy at the end of 2020. The number of dialysis patients has been increasing year by year, but the growth has slowed in recent years. As of 2020, 3031 more patients were on dialysis than in 2019 (Fig. 1, Additional file 1: Table S1). The prevalence rate per million population is on the rise and was 2754.3 in 2020, indicating that 1 of every 363.1 persons in the country was on dialysis (Fig. 1, Additional file 1: Table S1). Additional file 1: Table S1). According to the United States Renal Data System, Japan has the second highest

prevalence rate of dialysis patients worldwide after Taiwan [4].

There were 40,744 incident dialysis patients (i.e., those who newly commenced dialysis) in 2020, with a decrease of 141 (0.3%) from 2019 (Fig. 2, Additional file 1: Table S2). Dialysis was started in 93.9% of these patients by HD(F) and in 6.1% by PD (Table 1). The number of dialysis patients who died in 2020 was 34,414, with a decrease of 228 (0.7%) from the previous year (Fig. 2, Additional file 1: Table S2). In general, the number of patients in a given year is calculated by adding the number of incident patients to the number of patients in the previous year and subtracting the



Fig. 2 Trends in the number of incident dialysis patients and dialysis patient deaths, 1983–2020

number of deceased patients. However, the number of patients calculated does not match the actual number of patients. Patients who ceased dialysis after kidney transplantation were not included, and the number of incident patients may have been overestimated or the number of deceased patients underestimated.

Table 2 presents the number of dialysis patients by prefecture. However, caution is needed while evaluating these numbers considering that these data are based on location of the facility and not place of residence. Therefore, we cannot make a direct comparison between these data because of the many undetermined factors that confound the prefectural disparities.

3. Dialysis modalities

In 2020, HD accounted for 49.3% of the total dialysis population, HDF for 47.1%, PD for 3.0%, hemoadsorption

for 0.4%, home HD for 0.2%, and hemofiltration for 0.004% (Table 1). Since 2012, when online HDF was approved for reimbursement by the health insurance system, the number of patients receiving HDF has increased dramatically. According to the 2020 patient survey, 70.0% of patients on HDF were treated with online HDF followed by intermittent infusion HDF (28.3%), the prevalence of which has increased over the past few years (Fig. 3, Additional file 1: Table S3). The number of PD patients increased from 9920 in 2019 to 10,338 in 2020; 20.8% of these patients were receiving hybrid combination therapy with HD(F) to compensate for the decline in residual kidney function in terms of solute and/or fluid retention. The number of patients on home HD remained at 751 in 2020. Patients on PD or home HD in Japan represent 3.2% of the total dialysis population, which is low in comparison with other developed countries [4].

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| | facilities | facilities | 을 무 | HDF | 生 | НАD | HH | PD only | + HD 1/w | + HD 2/w | + HD 3/w | + HD in other frequencies | 8 | |
| Hokkaido | 261 | 258 | 7535 | 8167 | 0 | 105 | 10 | 442 | 103 | 2 | - | 5 | 16,370 | 3130.6 |
| Aomori | 41 | 41 | 1185 | 2346 | 0 | ſ | с | 87 | 13 | - | 0 | - | 3639 | 2937.0 |
| lwate | 44 | 43 | 2225 | 843 | 0 | 11 | 0 | 54 | 14 | 0 | 0 | <i>(</i> | 3148 | 2599.5 |
| Miyagi | 66 | 66 | 3583 | 2359 | 0 | 17 | 7 | 191 | 26 | - | 0 | 0 | 6184 | 2685.2 |
| Akita | 41 | 41 | 1274 | 862 | 0 | 0 | 2 | 45 | e | 0 | 0 | 0 | 2186 | 2277.1 |
| Yamagata | 35 | 35 | 1407 | 1283 | 0 | 9 | 12 | 64 | 7 | - | 2 | 0 | 2782 | 2602.4 |
| Fukushima | 73 | 71 | 2375 | 2774 | 0 | 19 | 0 | 58 | 22 | 10 | 0 | 0 | 5258 | 2867.0 |
| Ibaraki | 87 | 87 | 5109 | 3219 | 0 | 53 | 18 | 67 | 16 | 0 | 0 | 0 | 8482 | 2956.4 |
| Tochigi | 81 | 81 | 3434 | 2978 | 0 | 25 | 11 | 161 | 16 | ŝ | 0 | - | 6629 | 3427.6 |
| Gunma | 63 | 63 | 3782 | 2369 | - | 7 | 12 | 74 | 13 | 0 | 0 | 0 | 6258 | 3225.8 |
| Saitama | 197 | 195 | 7902 | 11,199 | 0 | 50 | 76 | 352 | 88 | 9 | 2 | 0 | 19,675 | 2678.0 |
| Chiba | 159 | 156 | 7962 | 7657 | , | 34 | 13 | 267 | 67 | 4 | - | 0 | 16,006 | 2545.9 |
| Tokyo | 445 | 441 | 14,381 | 17,620 | 0 | 129 | 113 | 955 | 296 | 13 | - | 13 | 33,521 | 2383.3 |
| Kanagawa | 271 | 268 | 11,509 | 9814 | 0 | 119 | 34 | 592 | 126 | 4 | m | 8 | 22,209 | 2403.6 |
| Niigata | 53 | 52 | 3298 | 1698 | 0 | 21 | m | 160 | 26 | 2 | 0 | 2 | 5210 | 2366.0 |
| Toyama | 42 | 42 | 1727 | 729 | 0 | 16 | С | 80 | 16 | <i>(</i> | 2 | Э | 2,577 | 2487.5 |
| Ishikawa | 41 | 41 | 1606 | 1113 | 0 | 19 | 5 | 64 | 7 | 0 | 2 | 0 | 2816 | 2485.4 |
| Fukui | 27 | 25 | 871 | 787 | 0 | 0 | e | 54 | 15 | 0 | 2 | 0 | 1732 | 2258.1 |
| Yamanashi | 33 | 33 | 1106 | 1242 | 0 | 9 | 2 | 19 | 10 | 0 | 0 | 0 | 2385 | 2944.4 |
| Nagano | 72 | 72 | 2860 | 2428 | ŝ | 9 | 13 | 80 | 13 | £ | 0 | - | 5407 | 2637.6 |
| Gifu | 74 | 74 | 2960 | 2120 | 0 | 16 | 24 | 81 | 19 | <i>(</i> | 0 | 0 | 5221 | 2636.9 |
| Shizuoka | 129 | 127 | 4427 | 6695 | 0 | 28 | 24 | 158 | 23 | 2 | 0 | | 11,358 | 3124.6 |
| Aichi | 198 | 197 | 9612 | 8627 | . | 55 | 47 | 576 | 135 | 23 | 1 | 0 | 19,077 | 2528.1 |
| Mie | 56 | 53 | 2406 | 1662 | 0 | 16 | 8 | 88 | 17 | 0 | 0 | ñ | 4200 | 2371.5 |
| Shiga | 40 | 39 | 1407 | 1706 | 0 | 32 | 38 | 146 | 14 | 0 | - | 0 | 3344 | 2364.9 |
| Kyoto | 79 | 77 | 2735 | 3527 | 0 | 55 | 14 | 169 | 54 | 7 | 2 | - | 6564 | 2544.2 |
| Osaka | 325 | 320 | 10,083 | 13,303 | 0 | 155 | 53 | 465 | 100 | 80 | 0 | 4 | 24,171 | 2733.3 |
| Hyogo | 201 | 196 | 6871 | 7266 | . | 88 | 69 | 168 | 34 | 00 | 0 | 0 | 14,505 | 2652.2 |
| Nara | 52 | 52 | 1698 | 1799 | 0 | 26 | 7 | 95 | 29 | 0 | 0 | 0 | 3654 | 2757.7 |
| Wakayama | 47 | 47 | 2173 | 830 | - | 17 | 31 | 99 | 13 | 0 | 0 | 0 | 3131 | 3392.2 |
| Tottori | 26 | 25 | 481 | 966 | 0 | 4 | 2 | 59 | 6 | c | 0 | 0 | 1554 | 2805.1 |
| Shimane | 30 | 30 | 638 | 1062 | 0 | 4 | e | 65 | œ | , - | 0 | 0 | 1781 | 2650.3 |
| Okayama | 65 | 65 | 2386 | 2760 | 0 | 27 | 9 | 206 | 25 | 4 | 2 | 0 | 5416 | 2865.6 |

| Table 2 (co | ntinued) | | | | | | | | | | | | | |
|----------------|-------------------|------------------------|-----------------|---------------|-----------|--------------|------------|------------------|------------------|---------------------|-----------------|------------------------------|-------------|----------------------|
| Prefecture | Surveyed | Responding | 무 | | | | | PD | | | | | Total | Prevalence (pmp) |
| | facilities | tacilities | 우 | HDF | 生 | HAD | 머머 | PD only | +HD 1/w | + HD 2/w | + HD 3/w | + HD in other frequencies | | |
| Hiroshima | 100 | 98 | 3710 | 3735 | 5 | 38 | 26 | 232 | 59 | 26 | с | | 7835 | 2797.2 |
| Yamaguchi | 59 | 56 | 1673 | 1881 | 0 | 4 | - | 105 | 26 | 6 | 0 | 0 | 3699 | 2754.3 |
| Tokushima | 40 | 40 | 1258 | 1429 | 0 | 10 | 5 | 74 | 88 | 3 | - | 2 | 2870 | 3986.1 |
| Kagawa | 50 | 50 | 1141 | 1443 | 0 | 7 | 7 | 122 | 62 | 3 | 0 | 0 | 2785 | 2928.5 |
| Ehime | 53 | 53 | 1858 | 2105 | 0 | 12 | 0 | 116 | 31 | , | 0 | 5 | 4128 | 3089.8 |
| Kochi | 39 | 39 | 750 | 1808 | 0 | 9 | 0 | 11 | ŝ | 3 | 0 | , – | 2582 | 3731.2 |
| Fukuoka | 200 | 197 | 8912 | 5952 | 0 | 53 | 21 | 655 | 55 | 0 | 0 | , - | 15,649 | 3045.1 |
| Saga | 37 | 37 | 1628 | 696 | 0 | 12 | 4 | 26 | 7 | 2 | 0 | 2 | 2650 | 3263.5 |
| Nagasaki | 64 | 63 | 2346 | 1513 | 0 | 24 | 00 | 108 | 17 | - | 2 | - | 4020 | 3061.7 |
| Kumamoto | 92 | 91 | 4171 | 2274 | 0 | 27 | 4 | 111 | 32 | 2 | - | c | 6625 | 3809.7 |
| Oita | 69 | 68 | 2691 | 1241 | 0 | 15 | 4 | 96 | 41 | 5 | 0 | - | 4094 | 3639.1 |
| Miyazaki | 66 | 64 | 2769 | 1136 | 0 | 7 | 0 | 45 | 5 | - | 0 | L | 3964 | 3704.7 |
| Kagoshima | 96 | 95 | 3462 | 1881 | | 16 | 2 | 157 | 43 | - | <i>—</i> | 8 | 5572 | 3506.6 |
| Okinawa | 74 | 73 | 1947 | 2618 | 0 | 19 | e | 122 | 36 | 0 | , - | 2 | 4748 | 3234.3 |
| Total | 4493 | 4437 | 171,324 | 163,825 | 14 | 1419 | 751 | 8188 | 1882 | 165 | 31 | 72 | 347,671 | 2754.4 |
| | | | (49.3) | (47.1) | (0.0) | (0.4) | (0.2) | (2.4) | (0.5) | (0.0) | (0.0) | (0.0) | (100.0) | |
| PD + HD patien | ts: patients trea | ated by the combine | ation of PD a | nd HD, HDF, I | HAD, or H | IF (excludir | ng those i | who underwe | ant only periton | ieal lavage) | | | | |
| HD. hemodialy: | is: HDF. hemod | liafiltration: HF. hem | nofiltration: F | HAD. hemoad | sorption | dialvsis: H | HD. home | . hemodialvsi | s: PD. peritonea | il dialvsis: pmp. i | aer million pop | ulation. HAD refers to | o hemodialv | sis therapy combined |
| with hemoadsc | rption using a | tandem-connected | l beta-2 micro | oglobulin ads | orptive c | olumn. Th | e numbei | rs of dialysis p | batients were ac | ljusted to pmp v | values based or | annual government | population | statistics |

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Fig. 3 Trends in the patients treated by HDF, 2009–2020. AFBF, acetate-free biofiltration; HDF, hemodiafiltration; IHDF, intermittent infusion hemodiafiltration

Regional variations in the distribution of dialysis modalities were also observed in each prefecture, which may reflect factors such as accessibility of health care services (Table 2).

There were 31,468 patients on nocturnal dialysis in 2020 (Table 1). Until the 2014 survey, the number of patients on nocturnal dialysis remained consistently between 41,000 and 42,000; however, in 2015, this number dropped dramatically to 33,370, possibly because of the addition of "dialysis during the hours permitted by insurance (starting after 5 p.m. or ending after 9 p.m.)"

to the definition of nocturnal dialysis in the 2015 survey. Since 2015, there has been a decrease in the total number of patients receiving nocturnal dialysis.

Chapter 2: Dynamics of chronic dialysis patients in 2020

1. Background characteristics

The 2020 patient questionnaire recorded the age and sex of 336,759 patients, 222,510 of whom were male and 114,249 were female. The mean age was 69.40 years





1983 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 yaer Fig. 5 Trend in the average age of the prevalent dialysis patients, 1983–2020



(Fig. 4, Additional file 1: Table S4). The mean age has increased over time (Fig. 5, Additional file 1: Table S5), with the highest proportion of both sexes being in the 70–74 year age category. Since 2012, the number of patients aged younger than 65 years has decreased, and since 2017, there has been a decrease in the number of patients aged younger than 70 years. These data indicate that the increase in the number of chronic dialysis patients in Japan is attributable to the rise in the proportion of patients aged 70 years or older (Fig. 6, Additional file 1: Table S6).

At the end of 2020, the average dialysis vintage was 7.37 years (6.84 years for men and 8.41 years for women). Patients with a dialysis vintage of less than 5 years accounted for 47.5% of the total dialysis population, while 8.5%, 2.3%, and 0.4%, respectively, had dialysis vintages

of 20, 30, and 40 years or more (Fig. 7, Additional file 1: Table S7). The patient with the longest dialysis history had received treatment for 52 years and 4 months. The trend of patient numbers by dialysis vintage indicates that the number of patients with a long dialysis vintage is increasing; as of 2020, 27.5% and 8.5% of patients had dialysis vintages of 10 and 20 years or more, whereas in 1992, 21.4% and 1.0%, respectively, had vintages of 10 and 20 years or more (Fig. 8, Additional file 1: Table S8).

In 2020, 39.5% of dialysis patients had diabetic nephropathy as their primary disease, followed by chronic glomerulonephritis (25.3%) and nephrosclerosis (12.0%) (Fig. 9, Additional file 1: Table S9). Since 2011, when diabetic nephropathy overtook chronic glomerulonephritis as the most prevalent underlying disease, the prevalence of diabetic nephropathy







Fig. 9 Distributions of prevalent dialysis patients by primary disease and sex, 2020. CAKUT, congenital anomalies of the kidney and urinary tract; PIH, pregnancy-induced hypertension; PKD, polycystic kidney disease; RPGN, rapidly progressive glomerulonephritis



Fig. 10 Trends in major primary diseases among prevalent dialysis patients, 1983–2020. PKD, polycystic kidney disease; RPGN, rapidly progressive glomerulonephritis

has steadily increased, although the rate of increase has slowed in recent years. The prevalence of chronic glomerulonephritis has decreased in a linear manner, whereas the prevalences of nephrosclerosis and unknown or undetermined primary disease have steadily increased (Fig. 10, Additional file 1: Table S10). It should be noted that the primary disease codes for the 2017 survey were modified in part and that the primary disease for each patient is determined primarily by the clinical judgment of the attending physician.

2. Causes of death

In 2020, the facility survey recorded 34,414 deaths and the patient survey documented the sex and cause of death for 33,069 patients. Heart failure was the leading cause of death (22.4%), followed by infection (21.5%), malignancy (9.0%), cachexia/uremia/senescence (6.2%), and cerebrovascular disease (5.9%). Other causes accounted for 11.1% of all deaths. In 32.0% of cases, death was attributable to cardiovascular disease, including heart failure, cerebrovascular disease, and myocardial infarction (Fig. 11, Additional file 1: Table S11).

Heart failure has been the leading cause of death since 1983, and the proportion has remained at around 25% since 1995, with a gradual decline since 2013. In contrast, deaths attributable to infectious diseases have increased since 1993 and remained at around 21.5% since 2015. Deaths from cerebrovascular disorders have shown a gradual downward trend since 1994. Deaths due to myocardial infarction peaked in 1997 at 8.4% and have since decreased gradually. Deaths due to malignancy, which bottomed out at 5.8% in 1987 and have been gradually increasing, have remained at around 9.0% since 2004. The proportion of cardiovascular deaths, which was 54.8% in 1988, has decreased steadily to 32.0% in 2020 (Fig. 12, Additional file 1: Table S12). Note that the cause-of-death classification codes used in this survey have been revised three times, first at the end of 2003 and subsequently in 2010 and 2017 [5].

3. Crude mortality rate

Based on the patient dynamics in the facility survey, the annual crude mortality rate was calculated using the following formula:

crude mortality rate = {number of deaths/(number of patients in the previous year + number of patients in the survey year)/2} $\times 100$ (%)



Fig. 11 Distributions of dialysis patients by cause of death and sex, 2020

% 40





1983 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 year Fig. 12 Trends in major causes of death, 1983–2020





<20 20≤,<25 25≤,<30 30≤,<35 35≤,<40 40≤,<45 45≤,<50 50≤,<55 55≤,<60 60≤,<65 65≤,<70 70≤,<75 75≤,<80 80≤,<85 85≤,<90 90≤,<95 95≤ age Fig. 14 Distribution of incident dialysis patients by age and sex, 2020</p>

age



Fig. 15 Trend in the average age of incident dialysis patients, 1983–2020



Fig. 16 Distributions of incident dialysis patients by primary disease and sex, 2020. CAKUT, congenital anomalies of the kidney and urinary tract; PIH, pregnancy-induced hypertension; PKD, polycystic kidney disease; RPGN, rapidly progressive glomerulonephritis

The crude mortality rate had remained between 9% and 10%, with the exception of 7.9% in 1989, when the completed questionnaire rate was exceptionally low. In 2020, the crude mortality rate was 9.9% (Fig. 13, Additional file 1: Table S13).

Chapter 3: Dynamics of incident patients in 2020

1. Clinical background

The 2020 patient survey recorded the age and sex for 38,549 incident patients. These patients comprised 26,983 men and 11,566 women with a mean age of 70.88 years (70.19 years for men and 72.48 years for women) (Fig. 14, Additional file 1: Table S14). The average age of both incident and prevalent patients is increasing annually (Fig. 15, Additional file 1: Table S15). The highest proportions of incident patients were found in men aged 70–74 years and women aged 80–84 years.

In 2020, diabetic nephropathy was the most prevalent primary disease among incident HD patients (40.7%), followed by nephrosclerosis (17.5%) and chronic glomerulonephritis (15.0%). This trend was similar to that in 2019, when nephrosclerosis replaced chronic glomerulonephritis as the second most prevalent primary disease. In 13.8% of patients, the primary disease was unknown or undetermined (Fig. 16, Additional file 1: Table S16). Since 1998, when diabetic nephropathy replaced chronic glomerulonephritis as the most prevalent primary disease, the number of patients with diabetes has steadily



Fig. 17 Trends in major primary diseases of incident dialysis patients, 1983–2020. PKD, polycystic kidney disease; RPGN, rapidly progressive glomerulonephritis



Fig. 18 Distributions of incident dialysis patient by cause of death and sex, 2020



increased. However, the number of patients with chronic glomerulonephritis and diabetic nephropathy has decreased, while that of patients with nephrosclerosis has been increasing in recent years (Fig. 17, Additional file 1: Table S17).

2. Causes of death

In the year of dialysis initiation, infection was the leading cause of death (26.3%), followed by heart failure (19.9%), cancer (10.9%), cerebrovascular disease (5.3%), cachexia/uremia/geriatric deterioration (4.7%), lung disease (2.9%), and myocardial infarction (2.9%). The total rate of cardiovascular-related deaths has decreased to 28.0% over time (Fig. 18, Additional file 1: Table S18). The trend in causes of death within the year of initiation of dialysis indicates that the leading cause of death in the 1990s was heart failure, which was surpassed by infectious diseases in around 2006. Since then, the proportion of deaths due to malignancy has remained at around 10% and deaths caused by cerebrovascular disease have remained at around 5% (Fig. 19, Additional file 1: Table S19).

Chapter 4: Quality management of dialysis fluid

1. Background

In 2006, a survey of the biological quality and management of dialysis fluid was initiated. Based on the results of that survey, the standard for biological quality of dialysis fluid was revised in 2008, with addition of a standard for chemical contamination in 2016 [6, 7]. These standards stipulate that the biological quality of dialysis fluid should be evaluated by the endotoxin level and TVC monthly for at least one dialysis machine and annually for all machines. "Standard dialysis fluid," which should have an endotoxin concentration of < 0.05 EU/mL and a TVC of < 100 colony-forming units (CFU)/mL, is the minimum quality of dialysis fluid that can be used for treatment. "Ultra-pure dialysis fluid" (UPD) is defined as dialysis fluid with an endotoxin level of < 0.001 EU/mL (less than the detectable level) and a TVC of < 0.1 CFU/mL. The standard recommends that all dialysis treatments should be performed using UPD.



Fig. 20 Distributions of facilities by ET measurement frequency and ET concentration in dialysis fluid, 2020. ET, endotoxin; EU, endotoxin unit



Chemical contamination and its management have been investigated since the 2017 survey, in addition to biological contamination of dialysis fluid. In 2020, 4422 facilities with at least one dialysis machine were surveyed for quality control of dialysis fluid.

2. Measurement of endotoxin level in dialysis fluid

A total of 4400 facilities provided responses regarding the frequency of endotoxin measurement in dialysis fluid. Of these, 3733 (84.8%) met the requirement to measure the endotoxin level at least once per month (Fig. 20a, Additional file 1: Table S20). The trend indicates that the proportion of facilities that test dialysis fluid for endotoxin at least once per month has been increasing. In 2008, when the water quality standards were promulgated, the proportion was 33.1%. In 2010, when the additional fee for dialysis water quality control was established, the proportion increased to 70.6% and has remained at around 85% since 2017 (Fig. 21, Additional file 1: Table S21).

Responses regarding the endotoxin level in dialysis fluid were received from 4358 facilities. The survey showed that 3746 facilities (86.0%) met the UPD quality standard of <0.001 EU/mL and 4248 (97.5%) met the "standard dialysis fluid" quality standard of <0.05 EU/ mL (Fig. 20b, Additional file 1: Table S20). The trend shows that, in 2020, as in the preceding years, the percentages with an concentrations below 0.001 EU/mL or below <0.05 EU/mL in dialysate increased relative to the previous year (Fig. 22, Additional file 1: Table S22). It should be noted that data for 2008 are missing; in that



Fig. 22 Trends in ET concentration in dialysis fluid, 2006–2020. ET, endotoxin; EU, endotoxin unit



Fig. 23 Distributions of facilities by TVC measurement frequency and TVC in dialysis fluid, 2020. TVC, total viable microbial count; CFU, colony-forming unit

year, the unit of measurement for the endotoxin level was changed from EU/L to EU/mL in the survey to be consistent with the international standard. This amendment increased the number of erroneous data in the survey for that year, leading us to the conclusion that the data for that year should be omitted.

3. Total viable count measurements in dialysis fluid

Of the 4393 facilities that responded to the survey regarding the frequency of TVC measurement, 3653 (83.2%) met the standard of measuring TVC at least once per month (Fig. 23a, Additional file 1: Table S23). As with the frequency of endotoxin measurement, the frequency

of TVC measurement has increased over the years, with a notable increase in 2010. However, the standard for frequency of TVC measurement was met by slightly fewer facilities than those that met the standard for frequency of endotoxin measurement (Fig. 24, Additional file 1: Table S24).

The "standard dialysis fluid" criterion of < 100 CFU/mL was met by 4270 facilities (99.5%), while the UPD standard of < 0.1 CFU/mL was met by 3481 (81.1%) (Fig. 23b, Additional file 1: Table S23). The percentages of TVC that were < 0.1 CFU/mL or < 100 CFU/mL had been increasing annually, but remained unchanged in 2020 (Fig. 25, Additional file 1: Table S25).



Fig. 24 Trends in dialysis fluid TVC measurement frequency, 2006–2020. TVC, total viable microbial count



Fig. 25 Trends in TVC in dialysis fluid, 2006–2020. TVC, total viable microbial count; CFU, colony-forming unit

4. UPD and standard dialysate achievement rates

The JSDT Standard of Fluids for Hemodialysis and Related Therapies defines the biological quality of dialysis as simultaneously meeting the endotoxin level and TVC standards in dialysis fluid [6, 7]. Information on both the endotoxin level and TVC in dialysis fluid was provided by 4286 facilities. Of these, 4172 (97.3%) met the "standard dialysis fluid" criterion of an endotoxin level of <0.050 EU/mL and a TVC of <100 CFU/mL in dialysis fluid, while 3323 (77.5%) met the UPD standard for an endotoxin level of <0.001 EU/mL and a TVC of <0.1 CFU/mL (Fig. 26, Additional file 1: Table S26). The achievement rate of UPD or standard dialysate has been increasing over time (Fig. 27, Additional file 1: Table S27).



Fig. 26 Distributions of facilities by ET concentration and TVC in dialysis fluid, 2020. CFU, colony-forming unit; ET, endotoxin; EU, endotoxin unit; TVC, total viable microbial count



Fig. 27 Trends in distributions of facilities by achievement of UPD and standard dialysis fluid levels, 2009–2020. The UPD standard requires both ET < 0.001 EU/mL and TVC < 0.1 CFU/mL. UPD, ultrapure dialysis fluid











Fig. 30 Distribution of facilities by measurement method for residual chlorine, 2020

5. Sources of water supply for dialysis and measures to prevent chemical contamination

Responses to the question regarding the dialysis water supply source were provided by 4401 facilities. At 3703 facilities, tap water is the most commonly used source of water, accounting for 84.1% of the total, followed by groundwater (384 facilities, 8.7%) and blended water (305 facilities, 6.9%) (Fig. 28, Additional file 1: Table S28).



Fig. 31 Distribution of facilities by awareness of the JSDT standard for chemical contaminants, 2020. JSDT, Japanese Society for Dialysis Therapy



Fig. 32 Distribution of facilities by measurement frequency of the JSDT standard for chemical contaminants, 2020. JSDT, Japanese Society for Dialysis Therapy

Compared with the previous year, there was little change in these percentages.

Information on the frequency of residual chlorine measurement was received from 4384 facilities, with 2803 (63.9%) reporting measuring daily, 889 (20.3%) measuring weekly, and 171 (3.9%) measuring monthly (Fig. 29, Additional file 1: Table S29). The number of facilities that measured daily was higher in 2020 than in the previous year. The number of facilities that do not measure residual chlorine decreased to 337 (7.7%). The majority of facilities (40.6%) measured both free and total chlorine, while 35.0% measured free chlorine only (Fig. 30, Additional file 1: Table S30).

Responses to the question regarding awareness of the JSDT chemical contamination standard were received from 4344 facilities; 87.1% of all respondents were "well aware" or "aware," representing an increase from the 85.6% in the previous year (Fig. 31, Additional file 1: Table S31) [7]. Regarding the frequency of measuring chemical contaminants specified in the water quality standards, 4204 facilities responded, with 42.3%

measuring once a year and 24.6% not measuring at all (Fig. 32, Additional file 1: Table S32). The number of facilities that measure chemical contaminants more than once per year increased, while the number of facilities that do not measure them decreased.

In summary, the frequency and method of chlorine measurement has improved, awareness of the chemical contamination standards for dialysis fluid has improved slightly, and the number of facilities that do not measure chemical contaminants has decreased. The continuous monitoring indicated in the 2020 survey is anticipated to improve compliance with the standard for quality management of dialysis fluid.

Chapter 5: COVID-19

1. Background

COVID-19, which originated in Wuhan, China in 2019, rapidly spread worldwide, and was declared a pandemic by the World Health Organization on 11 March 2020. On had tested positive for SARS-CoV-2 were alive and 151 had died as of 2020 (Additional file 1: Table S33). Ten patients whose SARS-CoV-2 test status was left blank on the questionnaire had COVID-19 listed as their cause of death. These 950 individuals are collectively referred to as patients with COVID-19 in this chapter.

Subpopulation on PD: of 9883 patients on PD, which included those on PD in combination with HD or HDF (hereafter referred to as patients on PD), 6861 responded to the question about whether they had been tested for SARS-CoV-2. The SARS-CoV-2 test was positive in 16 patients who were alive and 1 who had died as of 2020 (Additional file 1: Table S33). The cause of death was COVID-19 for 1 patient whose SARS-CoV-2 test status was left blank on the questionnaire. In total, 18 PD patients were diagnosed with COVID-19.

Based on these numbers, the incidence (Eq. 1) and mortality rate (Eq. 2) for the total dialysis population and for the PD subpopulation were calculated. The total population on dialysis was 332,599 in 2019 and 336,759 in 2020; the respective numbers in the PD subpopulation were 9528 and 9883.

Incidence = (patients with COVID-19¶) /(sum of total dialysis population as of 2019 and 2020 divided by 2) (1) $\times 100$ (%) Mortality rate = (sum of deceased patients who tested positive for SARS-CoV-2 and those whose cause of death was COVID-19) (2)

/(patients with COVID-19 \oint) × 100 (%)

15 January 2020, SARS-CoV-2, which causes COVID-19, was detected in Japan in a patient with pneumonia who had traveled to Wuhan City. By the end of September 2021, the number of new cases in Japan had increased rapidly between the first wave and fifth wave. The first COVID-19-positive dialysis patient was identified in Japan on 1 March 2020 and, as in the general population, the number of new patients increased between the first and fifth wave. This chapter summarizes a study that was conducted to determine the incidence and mortality rate of COVID-19 among patients on chronic dialysis.

2. Incidence of COVID-19 and mortality rate in patients on HD or PD

Total dialysis population: of 336,759 patients on dialysis (HD or PD) at the end of 2020, 274,946 responded to a question regarding whether they had been tested for COVID-19. Among the responders, 789 of those who Here, ¶ denotes patients with COVID-19, which was the sum of (1) patients who were alive or deceased in 2020 and who tested positive for SARS-CoV-2 and (2) patients whose SARS-CoV-2 test status was left blank on the questionnaire and whose cause of death was COVID-19.

The incidence rate of COVID-19 was 0.28% in the total dialysis population and 0.19% in the subpopulation on PD, with respective mortality rates of 16.9% and 11.1%. The mortality rate in PD patients was lower than that in the total dialysis population, possibly because the PD patients were younger than the total dialysis population and older age is a predictor of death due to COVID-19. The mean age was 60.44 years in patients on PD and 67.39 years in the total dialysis population that tested positive for SARS-CoV-2.

The dialysis modality (i.e., HD or PD) could be left blank on the questionnaire for patients who had died within the year. Seventy-nine (49.1%) of 161 deceased



Fig. 33 Number of COVID-19 infections and COVID-19-related mortality rate in dialysis patients by age group, 2020

Table 3 Number of patients infected with COVID-19 according to dialysis vintage, 2020

| | Dialysis | vintage (years) | | | | | | |
|--------------------|----------|-----------------|-----------|------------|------------|-------|------|-------|
| | <2 | 2 to < 5 | 5 to < 10 | 10 to < 15 | 15 to < 20 | 20–25 | ≥25 | Total |
| Patients (n) | 260 | 237 | 220 | 114 | 53 | 36 | 30 | 950 |
| Deaths (n) | 36 | 44 | 40 | 17 | 15 | 5 | 4 | 161 |
| Mortality rate (%) | 13.8 | 18.6 | 18.2 | 14.9 | 28.3 | 13.9 | 13.3 | 16.9 |

Table 4 Number of patients infected with COVID-19 accordingto diabetes status, 2020

| | With diabetes | Without diabetes | Subtotal | Unknown | Total |
|-----------------------|------------------|---------------------|----------|---------|-------|
| Patients (<i>n</i>) | 529 | 300 | 829 | 121 | 950 |
| Deaths (n) | 80 | 19 | 99 | 62 | 161 |
| Mortality rate (%) | 15.1 | 6.3 | 11.9 | 51.2 | 16.9 |

patients who tested positive for COVID-19 or whose cause of death was COVID-19 did not have their dialysis modality documented. It should be noted that the total number of patients on dialysis may have included some PD patients. 3. Sex, age, dialysis vintage, and mortality rate among dialysis patients with COVID-19

Of the 950 patients with COVID-19, 682 were male and 268 were female. Among these patients, 114 men and 47 women died, giving mortality rates of 16.7% and 17.5%, respectively (Additional file 1: Table S34). Figure 33 shows the mortality rates by age group. In dialysis patients, mortality rates were higher in the younger age groups than in the general population (4.4% for dialysis patients aged 30–44 years and 6.9% for those aged 45–59 years). The mortality rate increased with age and was particularly high among those aged 75 years or older (Fig. 33, Additional file 1: Table S34).



Fig. 35 Presence or absence of malignant tumor by sex, 2020

94.0%

(154,774)

The mortality rate was also high among patients with a dialysis vintage of 15–19 years, probably because of the number of infected patients and their advanced age (Table 3).

4. Diabetes mellitus status and mortality rate in patients with COVID-19 infection

Mortality rates were calculated for 829 of the 950 patients with COVID-19 according to whether or not they were documented to have diabetes mellitus. A

high proportion (63.8%, n = 529) of the patient population had diabetes. Patients with diabetes had a higher mortality rate than those without diabetes (15.1% versus 6.3%) (Table 4).

95.5%

(80,453)

5. Monthly trend in the number of patients with COVID-19 between March and December 2020

Information on the month of the positive test was provided for 851 of the 950 patients with COVID-19. Between March and December 2020, 612 male and





Fig. 37 Types of malignant tumors by age, 2020

239 female patients were infected. The trend in the number of dialysis patients who were infected with COVID-19 showed three peaks in April, August, and November–December 2020, which corresponded to the first, second, and third waves (Fig. 34, Additional file 1: Table S35). The third wave peaked in the general population in January 2021. The trend in the number of patients with COVID-19 reflects that in the general



Fig. 38 Types of malignant tumors by dialysis vintage, 2020

population, indicating that community-acquired infection was the primary route among dialysis patients, rather than any specific dialysis-related route.

Chapter 6. Malignancy

1. Background

According to the 2019 survey, heart failure was the leading cause of death among chronic dialysis patients in Japan (22.7%), followed by infection (21.5%), malignancy (8.7%), cerebrovascular disease (5.7%), and myocardial infarction (3.9%) [8]. In the general Japanese population, the leading causes of death are malignancy (27.3%), cardiac disease (15.0%), senility (7.8%), cerebrovascular disease (7.7%), pneumonia (6.9%), and aspiration pneumonia (2.9%) [9]. Therefore, the causes of death differ markedly between the dialysis population and the general population. In recent years, cancer-related deaths have been increasing annually in the general population but have remained at around 9% in patients on dialysis. Even though it is thought that cancer is more common in dialysis patients than in the general population, this observation has not been tested adequately in large-scale studies. Therefore, we surveyed the prevalence of malignancy in dialysis patients during 2020. This is the first such survey conducted by the JSDT since 1987.

2. Presence and type of malignancy

Of 336,759 patients on dialysis at the end of 2020, 248,871 (73.9%) answered the question regarding whether they had a current malignancy. Some type of cancer was reported by 9867 (6.0%) of the 164,641 male patients and 3777 (4.5%) of the 84,230 female patients, indicating a higher prevalence among men on dialysis (Fig. 35, Additional file 1: Table S36).

The type of cancer was reported by 12,964 of 13,644 patients with current malignancy. Considering that a patient may have multiple malignancies, up to three responses were allowed. Note that the denominator of each percentage mentioned in the remainder of this section represents the "number of patients who responded to the question regarding type of cancer" and that the percentages do not add up to 100.

Urological malignancies ranked first among men (43.8%), followed by malignancies of the gastrointestinal tract (29.5%) and respiratory system (14.7%). Breast and endocrine cancers were the most prevalent malignancies among women (25.8%), followed by gastrointestinal (25.4%) and urological (14.5%) malignancies (Fig. 36, Additional file 1: Table S37). The percentage of urological



Fig. 39 Duration from kidney donation to initiation of dialysis in kidney transplant donors, 2020

malignancies among men was high because of the inclusion of prostate cancer in this category. Figures 37 and 38 show the types of cancer according to age group and dialysis vintage, respectively (Supplementary Tables 38 and 39).

The 1987 survey did not investigate the prevalence of malignancy by sex. At the end of 1987, 1041 of the 80,075 patients on dialysis had malignancies, and 974 provided information about their sites. The most common malignancies by site were stomach cancer (28.4%), followed by renal cancer (10.2%) and liver and intrahepatic bile duct cancer (7.4%) [10]. The prevalence of malignant tumors in dialysis patients cannot be adequately characterized by studies based on cause of death, given that recent advances in medicine have made it possible to detect and treat malignant tumors at an earlier stage. Therefore, some cancers can be cured, and not all malignancies are fatal. Malignant tumors are more common in transplant recipients than in the general population. As in transplant recipients, the majority of reports suggest that malignant tumors are more prevalent in dialysis patients than in the general population, but some studies have found otherwise [11-14]. The standardized incidence ratio should be used to determine whether malignancies are more common in dialysis patients than in the general population. Further studies of malignancy in patients on dialysis should consider whether the malignancy was detected before or after initiation of dialysis.

Chapter 7: History of kidney donation for living-donor transplantation

1. Background

Almost 90% of the kidney transplants performed annually in Japan are from living donors [15]. Owing to the

chronic donor shortage, kidney transplants are also performed using marginal donors who may be old, hypertensive, or diabetic. Donor safety is crucial in living-donor kidney transplantation. A questionnaire-based survey by the Japanese Society for Clinical Renal Transplantation and the Japanese Society for Transplantation identified one or two patients who started dialysis within 7 years of kidney donation; however, the response rate to that questionnaire was low [15]. The safety of kidney transplant donors also affects the options for renal replacement therapy. Therefore, in 2019, we included further questions in the survey of patients on maintenance dialysis to determine whether they had previously donated a kidney for transplantation.

Given that the 2019 survey was the first to investigate a history of kidney donation, some facilities misunderstood the question and gave incorrect responses. For example, 21 of the 181 patients who reported a history of donating a kidney transplantation had donated during the same year that dialysis was initiated or in the following year. Therefore, an alert message was displayed when entering data in the Excel file if the kidney had been donated in the year after starting dialysis. Erroneous data of this nature were excluded in the 2020 survey. The JSDT headquarters sent additional inquiries directly to the facilities to confirm the history of kidney donation and its month and year. In the 2019 survey, the inquiry was sent to facilities with multiple patients who had a history of kidney donation. In contrast, in the 2020 survey, an additional inquiry was sent to all facilities with at least one patient who had a history of kidney donation. Before the additional inquiry, 616 patients at 175 facilities were described as having a history of kidney donation, and 604 patients at 163 facilities responded to the additional inquiry. As a result of the additional inquiry, 507 patients were found to have no history of kidney donation and 95 to have a history of donating a kidney, with data on history of kidney donation missing for two patients. The facilities for the remaining 12 patients did not respond to the additional inquiry and were recorded as having a history of kidney donation, as previously reported.

2. Renal donation status

Of the 336,759 patients on maintenance dialysis as of 2020, 247,691 (73.6%) provided information about their kidney donation status. Among these 247,691 patients, 107 (0.043%) reported that they had donated a kidney for transplantation (Additional file 1: Table S40). This number was lower than the 160 recorded at the end of 2019, possibly as a result of the additional question asked in 2020.

3. Interval between kidney donation and dialysis

The year and month of kidney donation or the year of kidney donation was available for 97 of 107 patients (90.7%). The average interval between kidney donation and initiation of dialysis was 19 years and 2 months (standard deviation: 9 years and 7 months). Dialysis was started within less than 5 years after kidney donation in 3 patients (3.1%) and within 5–10 years in 16 (16.5%)(Fig. 39, Additional file 1: Table S41). We assumed that the month of kidney donation was June of the same year for 53 of the 97 patients who did not provide information regarding the month of kidney donation. In 2019, dialysis was started within 5 years of kidney donation in 13 patients (12.5%) and within 5-10 years in 19 (18.3%). Fewer patients started dialysis within 5 years of kidney donation in 2020 than in 2019, presumably because of incorrect interpretation of the questionnaire in 2019. Three patients starting dialysis within 5 years of donating a kidney in 2020 is comparable with the report by the Japanese Society for Clinical Renal Transplantation and Japanese Society for Transplantation that one or two patients started dialysis within 7 years of kidney donation [15].

4. Sex and primary disease

Fifty-seven (53.3%) of the 107 patients who responded that they had donated a kidney for transplantation were male and 50 (46.7%) were female (Additional file 1: Table S41). The numbers of patients with diabetic nephropathy, chronic glomerulonephritis, and nephrosclerosis as the primary disease were 24 (22.4%), 26 (24.3%), and 22 (20.6%), respectively. Unlike in the total dialysis population, the proportions of these major primary diseases were comparable among the patients who had donated a kidney (Additional file 1: Table S42).

Conclusions

The results of the 2020 JRDR annual survey indicate that although the number of patients on maintenance dialysis in Japan has increased to 347,671, the rate of increase is slowing. This trend is of interest in view of a report indicating that the number of dialysis patients would peak in 2021 [16]. The average age of incident patients was 70.88 years and that of prevalent patients was 69.40 years. Diabetic nephropathy was the most common primary disease in both incident and prevalent individuals, followed by nephrosclerosis, which was also the second most common primary disease among incident patients since 2019. The percentage of patients with nephrosclerosis is increasing among both incident and prevalent patients, whereas the percentage of incident patients with diabetic nephropathy is decreasing.

Our survey found that both the biological quality of the dialysis fluid and the percentage of facilities that met the JSDT criteria were high and continuing to improve. Moreover, the percentages of facilities monitoring chemical contaminants and residual chlorine in compliance with the JSDT standard have been steadily increasing since they were first investigated in 2017.

The number of patients treated with HDF or PD is continuing to increase. The proportion of patients on PD combined with HD or HDF (hybrid therapy), a unique modality in Japan, is about 20% of the total PD population and has remained unchanged over the past several years.

In the 2020 survey, dialysis patients were investigated for the first time regarding COVID-19, which has evolved into one of the most critical issues in society. Since the first report of a positive case in a patient on dialysis in March 2020, the number of patients testing positive for SARS-CoV-2 has shown a pattern comparable with that seen in the general population. The COVID-19-related mortality rate is much higher in patients on dialysis than in the general population, especially among the younger age group. Infection and mortality rates were lower in patients on PD and those without diabetes than in patients on total dialysis and those with diabetes. More research is needed to evaluate the various treatment modalities and primary diseases while considering dialysis patients' individual characteristics.

For the first time since 1987, the prevalence rate of malignancy was investigated as part of the 2020 survey and included both sex and type. The prevalence rate was 6.0% in men and 4.5% in women. Renal and urological malignancies, including prostate cancer, were the most common types in men. Cancers of the breast and endocrine system were the most prevalent types seen in women. The second most common origin of malignancy was the gastrointestinal tract in both sexes. Some malignancies can now be detected in their early stages and are curable, so are not necessarily fatal. This survey has provided detailed information on the prevalence of malignancies in patients on dialysis that could not be acquired in a survey of causes of death.

As in 2019, the 2020 survey investigated history of kidney donation. Additional inquiries were made of facilities that had treated at least one patient with a history of kidney donation to ensure that the data obtained were as accurate as possible. The decrease in the number of patients who started dialysis shortly after kidney donation in 2020 indicates that the additional inquiries improved the accuracy of the survey. In total, 107 patients had a history of kidney donation. A comprehensive assessment of these individuals will provide helpful information that may be used to improve the health of living kidney transplant donors.

Present issues and challenges in renal replacement therapy were identified in the responses to the new questionnaire items included in this survey. A more detailed evaluation with adjustment for patient background factors should clarify the characteristics of the underlying diseases and conditions in dialysis patients.

Abbreviations

| AFBF | Acetate-free biofiltration |
|------------|--|
| CFU | Colony-forming unit |
| COVID-19 | Coronavirus disease 2019 |
| HD | Hemodialysis |
| HDF | Hemodiafiltration |
| IHDF | Intermittent infusion hemodiafiltration |
| JRDR | Japanese Society for Dialysis Therapy (JSDT) Renal Data Registry |
| JSDT | Japanese Society for Dialysis Therapy |
| PD | Peritoneal dialysis |
| SARS-CoV-2 | Severe acute respiratory syndrome coronavirus 2 |
| TVC | Total viable microbial count |
| UPD | Ultra-pure dialysis fluid |
| WADDA | Web-based analysis of dialysis data archives |

Supplementary Information

The online version contains supplementary material available at https://doi. org/10.1186/s41100-024-00531-5.

Additional file 1. Supplementary tables 1–42.

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Author contributions

All authors participated in the design of this survey. NH, MA, MT, NJ, and SG wrote the draft version of the manuscript. All authors contributed to and approved the final version.

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Availability of data and materials

The data and materials in this article can be used freely without modifications as long as they are cited and the data obtained from the JRDR are identified.

Any use of the data and materials with modifications or recalculations must include the following disclosure: "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 JSDT ethics committee approved the JRDR survey (approval number 1). The aims of the JSDT Renal Data Registry were explained in detail to the participating patients via the dialysis facilities. The need for informed consent was waived in view of the data having already been recorded before the survey, the noninterventional nature of the research, and the anonymity of the data analyzed. Therefore, there was no risk to the privacy of the dialysis facilities or their patients. The data presented in the current manuscript do not contain any images, videos, or voice recordings that might identify an individual patient.

Consent for publication

Not applicable.

Competing interests

Professor Masanori Abe MD is the deputy editor of this journal. Professor Norio Hanafusa MD is an associate editor for this journal.

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