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Vascular access dysfunction incidence among Japanese dialysis patients from NDB Open Data Japan

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Vascular access (VA) dysfunction affects the quality of care in end-stage renal disease (ESRD) patients undergoing hemodialysis. However, comprehensive nationwide data in Japan are limited. Therefore, we estimated VA dysfunction and recurrence and examined their associations with sex, age, and regional variation using the National Database Open Data Japan (NDB Open). We conducted a population-based observational study using the NDB Open for fiscal years 2020–2022. We identified ESRD patients who underwent VA-related procedures based on claims codes. We also calculated annual VA dysfunction rates and 3-month recurrence rates. We used multiple regression models, adjusted for sex, age, and the fiscal year, to examine associations; the regional differences were also evaluated. The average annual VA dysfunction rate was 74.0% (standard error [SE], 1.7%), with a 3-month recurrence rate of 16.9% (SE, 0.5%). Females and older patients showed higher rates. Age correlated positively with the VA dysfunction rate (ρ = 0.827–0.941). VA dysfunction rates varied across prefectures. In Japanese ESRD patients, VA dysfunction showed sex- and age-related differences, along with regional variations. These findings may inform future prevention strategies and research utilizing detailed clinical data.

Keywords Vascular access dysfunction, Hemodialysis, End-stage renal disease, Regional variation, Population-based study, NDB open data Japan

Abbreviations

AK	Artificial kidney
AVF	Arteriovenous fistula
AVG	Arteriovenous graft
CVC	Central venous catheters
ESRD	End-stage renal disease
HD	Hemodialysis
Management fee for dialysis	Outpatient medical management for chronic maintenance dialysis
MHLW	Ministry of Health, Labor, and Welfare
NDB	National Database of Health Insurance Claims and Specific Health Checkups of Japan
NDB Open	NDB open data Japan
VA	Vascular access
VAIVT	Vascular access interventional therapy
VA recurrence	VA dysfunction recurrence within three months after the initial intervention

End-stage renal disease (ESRD) poses a growing global health challenge and is characterized by the irreversible loss of kidney function[1,2]. ESRD primarily results from chronic conditions such as diabetes, hypertension, and glomerulonephritis. The treatment options include ongoing hemodialysis (HD) and kidney transplantation. Globally, millions rely on these interventions, with Japan alone having over 350,000 patients[3] dependent on renal replacement therapy, predominantly HD, for survival.

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The efficacy of HD relies on vascular access (VA) functionality[4]. VAs are surgically created as either arteriovenous fistulas (AVFs) or grafts (AVGs). AVFs, which directly connect an artery to a vein, are preferred for their durability and lower complication rates. When AVFs are not viable, AVGs, made with artificial blood vessels, serve as alternatives. However, all VAs are susceptible to complications such as thrombosis and infection[5,6], which can compromise dialysis efficacy. Therefore, appropriate Proper VA management is crucial for optimal patient outcomes.

VA dysfunction is a critical issue in dialysis management[7]. Nonetheless, comprehensive epidemiological data regarding its incidence and regional variations are lacking. In Japan, the Japanese Society for Dialysis Therapy conducts annual surveys that provide valuable information on dialysis patient demographics and trends; however, these surveys do not include specific items related to VA dysfunction[3]. Although international studies on VA dysfunction have been conducted[1], such data have not been collected from Japanese surveys. Consequently, comprehensive data on VA dysfunction in Japan are unavailable, highlighting the need for further research on this topic.

Research on ESRD patient outcomes and VA dysfunction using large-scale healthcare databases is emerging globally. The United States Renal Data System[1] and the European Renal Association Registry[8] have pioneered the analyses of VA dysfunction rates, causes, and regional variations. Although such a comprehensive national database is not yet available in Japan, VA-related procedures, including surgical interventions for dysfunction, have been recorded in medical fee claims[9]. These data are compiled in the National Database of Health Insurance Claims and Specific Health Checkups of Japan (NDB)[10], which can be accessed under certain restrictions. To promote the wider use of these valuable healthcare data while maintaining patient privacy, the Ministry of Health, Labour and Welfare (MHLW) offers a publicly accessible version known as NDB Open Data Japan (NDB Open)[11]. This dataset contains aggregated information from the NDB. Analyzing these claims can yield valuable insights into VA dysfunction patterns in Japan.

This study aimed to quantify the incidence rate of VA dysfunction in Japan using the NDB Open. We established a definition for VA dysfunction based on insurance claims and clinical conditions. These results offer insights into VA dysfunction patterns in one of the world's largest dialysis populations.

Results

Characteristics

Table 1 presents the data on ESRD patients, VA dysfunction and VA dysfunction recurrence within three months after the initial intervention (VA recurrence) from FY 2020 through FY 2022. The average number of ESRD

	Vascular access dysfunction			Vascular access recurrence dysfunction		
Characteristic	ESRD	Dysfunction	Frequency [%]	Dysfunction	Re-Dysfunction	Frequency [%]
Fiscal Year	299,373 (499)	221,599 (4,597)	74.0 (1.7)	184,008 (2,871)	37,590 (1,768)	16.9 (0.5)
Sex						
Male	197,710 (345)	137,133 (3,733)	69.4 (0.1)	115,048 (2,517)	22,085 (1,222)	16.1 (0.1)
Female	101,663 (731)	84,466 (969)	83.1 (0.1)	68,961 (398)	15,505 (571)	18.4 (0.1)
Age (Years)						
20–24	76 (12)	20 (2.1)	31.4 (6.9)	20 (2.1)	0 (0)	0 (0)
25–29	213 (35)	50 (3.6)	27.8 (5.5)	50 (3.6)	0 (0)	0 (0)
30–34	540 (101)	214 (31)	44.1 (5.4)	187 (19)	27 (2.3)	12.9 (0.7)
35–39	1,289 (241)	526 (47)	45.4 (5.0)	468 (42)	58 (6.0)	10.9 (0.6)
40–44	2,702 (543)	1,273 (119)	53.4 (6.3)	1,082 (111)	192 (12)	15.4 (1.0)
45–49	5,735 (1,170)	2,963 (343)	57.5 (5.8)	2,510 (316)	453 (30)	15.8 (1.0)
50–54	8,864 (1,742)	4,859 (658)	58.9 (4.2)	4,150 (587)	709 (71)	15.0 (0.6)
55–59	10,969 (2,050)	6,366 (951)	60.6 (3.0)	5,402 (820)	963 (134)	15.3 (0.5)
60–64	13,498 (2,260)	8,377 (1,022)	64.8 (3.4)	7,073 (900)	1,305 (126)	15.9 (0.6)
65–69	18,999 (2,870)	13,156 (1,511)	71.4 (2.9)	11,024 (1,327)	2,131 (190)	16.4 (0.6)
70–74	27,833 (4,076)	21,069 (2,533)	77.4 (2.5)	17,545 (2,205)	3,524 (335)	17.0 (0.6)
75–79	22,730 (3,139)	18,869 (2,184)	84.5 (2.4)	15,590 (1,886)	3,279 (303)	17.6 (0.5)
80–84	19,457 (2,295)	17,190 (1,764)	89.3 (2.2)	14,080 (1,497)	3,109 (277)	18.2 (0.5)
85–89	12,294 (999)	11,550 (879)	94.2 (1.6)	9,374 (744)	2,176 (145)	18.9 (0.5)
90≤	4,487 (126)	4,319 (191)	96.1 (2.4)	3,451 (133)	868 (64)	20.0 (0.8)

Table 1. Characteristics of patients with end-stage renal disease (ESRD) patients, their vascular access (VA) dysfunction, and its recurrence within three months after the initial intervention. Values are presented as total number (annual SE) or percentages (SE). The frequency of VA dysfunction was calculated as follows: (VA dysfunction/ESRD) × 100. The frequency of VA dysfunction recurrence within 3 months of the initial intervention (VA recurrence) was calculated as (VA recurrence/VA dysfunction) × 100. Abbreviations: ESRD, end-stage renal disease; VA, vascular access; VA recurrence, VA dysfunction recurrence within 3 months of initial intervention.

patients over this period was 299,373 (standard error [SE]: 499; 95% confidence interval [CI]: 298,395–300,351), with an average of 221,599 (SE: 4,597; CI: 212,589–230,609) cases of VA dysfunction. Of these, 37,590 (SE: 1,768) experienced VA recurrences.

The average VA dysfunction rate over three years was 74.0% (SE: 1.7%; 95% CI: 70.7%-77.3%) per year, while the average VA recurrence rate within 3 months was 16.9% (SE: 0.5%; 95% CI: 15.9%-17.9%)) per year. Additionally, a one-way analysis of variance (ANOVA) revealed statistically significant differences in both rates across age groups (VA dysfunction rate: $F = 345.1$, $p < 0.001$; VA recurrence rate: $F = 890.4$, $p < 0.001$).

VA dysfunction ratio by age and sex

Figure 1 delineates the VA dysfunction rates categorized by sex and age (Fig. 1a) and within a 3-month period following the initial VA dysfunction rates (Fig. 1b) from FY 2020 to FY 2022. VA dysfunction rates increased with advancing age and were consistently higher in females than in males. Similarly, VA recurrence rates showed a higher rate in females and also tended to increase with age.

We constructed multiple regression models to analyze VA dysfunction and its recurrence using sex, age group, and FY as explanatory variables. The adjusted R2 values for the VA dysfunction and recurrence models were 0.977 and 0.981, respectively (Tables 2, 3). The VA dysfunction model showed significant increases in FY 2021 ($p < 0.05$) and FY 2022 ($p < 0.01$). Women aged 40 years and older experienced a pronounced increase (Age 75–79 years: $p < 0.001$, Age ≥ 90 years: $p < 0.001$). Although men consistently had lower overall values ($p < 0.001$), the interaction between sex and age was significant across many age groups, with the sex-based differences narrowing with age (Table 2).

In the VA recurrence model, recurrence rates significantly increased after FY 2021 ($p < 0.001$), with a notable rise observed in individuals aged 30 years and older (Age 30–34 years: $p < 0.001$ and older groups). However, among men aged 30–34 and 40–44 years, the interaction between sex and age showed negative values, indicating a milder increase compared to women (Sex M, Age 30–34 years, $p < 0.05$; Sex M, Age 40–44 years, $p < 0.001$) (Table 3).

As a supplementary analysis, we evaluated sex differences in the incidence and recurrence rates of VA dysfunction using the Cochran-Mantel–Haenszel test. The results showed that men had significantly lower risks of both VA dysfunction incidence (OR, 0.686; 95% CI, 0.680–0.692) and VA dysfunction recurrence (OR, 0.690; 95% CI, 0.681–0.698; $p < 0.01$ (Supplementary Table 3). Additionally, Spearman's rank correlation analysis revealed strong positive correlations between age and VA dysfunction incidence across all fiscal years ($\rho = 0.827$–0.941, $p < 0.01$), indicating that this relationship remained consistent over time (Supplementary Table 4).

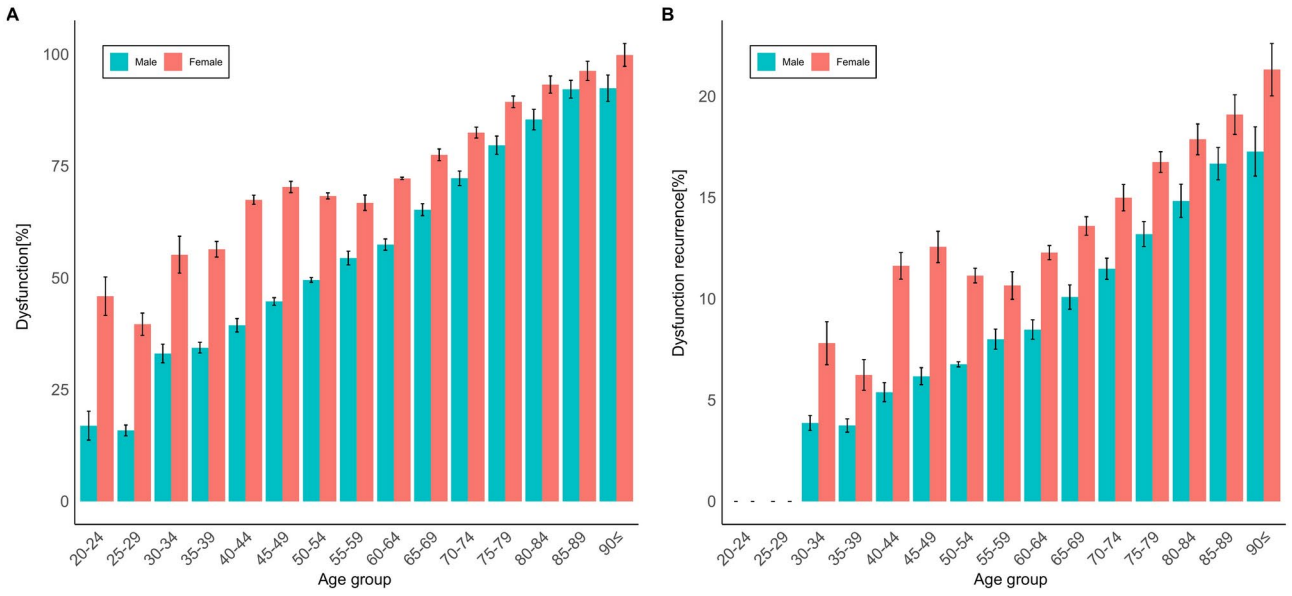

Fig. 1. Vascular access (VA) dysfunction rates and recurrence rates within three months after the initial intervention by sex and age are depicted for the fiscal years 2020 through 2022. (**a**) Initial VA dysfunction rate by age. (**b**) VA dysfunction recurrence within three months after the initial intervention by age In all the figure parts, the green and orange bars represent the male and female patients, respectively. The X-axis represents age categories in 5-year increments from 20- to 90 + years. The Y-axis quantifies the incidence of VA dysfunction (incidence/% of patients with end-stage renal disease) in these demographically segmented cohorts. In all the figure parts, trends toward sex and age differences exist in the incidences of VA dysfunction. Abbreviations: VA, vascular access.

Variable	Estimate	SE	95% CI	p-value
FYs				
2021	0.014	0.007	[0.000, 0.027]	0.045 *
2022	0.018	0.007	[0.005, 0.032]	0.008 **
Sex				
M	− 0.289	0.021	[− 0.332, − 0.247]	< 0.001 ***
Age				
25–29	− 0.063	0.021	[− 0.106, − 0.020]	0.005 **
30–34	0.015	0.021	[− 0.028, 0.058]	0.490
35–39	0.043	0.021	[0.000, 0.085]	0.051
40–44	0.099	0.021	[0.057, 0.142]	< 0.001 ***
45–49	0.119	0.021	[0.076, 0.162]	< 0.001 ***
50–54	0.113	0.021	[0.070, 0.156]	< 0.001 ***
55–59	0.102	0.021	[0.060, 0.145]	< 0.001 ***
60–64	0.141	0.021	[0.098, 0.184]	< 0.001 ***
65–69	0.180	0.021	[0.138, 0.223]	< 0.001 ***
70–74	0.216	0.021	[0.173, 0.259]	< 0.001 ***
75–79	0.267	0.021	[0.224, 0.310]	< 0.001 ***
80–84	0.295	0.021	[0.252, 0.337]	< 0.001 ***
85–89	0.313	0.021	[0.270, 0.356]	< 0.001 ***
≥ 90	0.326	0.021	[0.284, 0.369]	< 0.001 ***
Age·Sex				
M, 25–29	0.052	0.030	[− 0.008, 0.113]	0.090
M, 30–34	0.108	0.030	[0.048, 0.168]	0.001 ***
M, 35–39	0.094	0.030	[0.034, 0.155]	0.003 **
M, 40–44	0.071	0.030	[0.011, 0.131]	0.022 *
M, 45–49	0.097	0.030	[0.037, 0.158]	0.002 **
M, 50–54	0.145	0.030	[0.085, 0.206]	< 0.001 ***
M, 55–59	0.192	0.030	[0.132, 0.253]	< 0.001 ***
M, 60–64	0.179	0.030	[0.119, 0.240]	< 0.001 ***
M, 65–69	0.202	0.030	[0.141, 0.262]	< 0.001 ***
M, 70–74	0.222	0.030	[0.162, 0.283]	< 0.001 ***
M, 75–79	0.228	0.030	[0.168, 0.288]	< 0.001 ***
M, 80–84	0.241	0.030	[0.181, 0.302]	< 0.001 ***
M, 85–89	0.272	0.030	[0.212, 0.333]	< 0.001 ***
M, ≥ 90	0.255	0.030	[0.195, 0.316]	< 0.001 ***

Table 2. Risk factors for vascular access (VA) dysfunction. The intercept is omitted from the table. Model fit statistics: Adjusted $R^2 = 0.9774$ (F-statistic: $p < 0.001$). Significance codes: *** $p < 0.001$; ** $p < 0.01$; * $p < 0.05$. The estimates represent changes in the risk of VA dysfunction. Age·Sex interaction terms represent the additional effect for males in each age group compared to females. The analysis was based on n = 90 aggregated observations (3 fiscal years × two sex categories × 15 age groups). The reference categories were FY2020, Female sex, and an age group 20–24 years.

VA dysfunction rate by region

Figure 2 presents the variation in VA dysfunction rates across the prefectures (Fig. 2a) and within a timeframe of 3 months (Fig. 2b), revealing pronounced regional disparities in both aggregate and short-term VA dysfunction rates.

To examine these regional variations further, we conducted additional analyses using standardized data and spatial autocorrelation techniques. Hierarchical clustering of the standardized VA dysfunction rates relative to the ESRD prevalence identified two principal clusters (Supplementary Fig. 1). Additionally, local Moran's I analysis for spatial autocorrelation revealed limited clustering of treatment selections, with a few exceptions (Supplementary Fig. 2 at 0.10 significance level).

With a few exceptions, we observed no distinct clustering of treatment selections. These findings suggest that treatment choices vary between adjacent regions, implying that treatment strategies may be adopted independently at the prefectural level.

Discussion

This study analyzed the incidence rate of VA dysfunction in ESRD patients in Japan using the NDB Open Data, identifying differences by sex and age (Table 1 and Fig. 1). The findings revealed significantly higher rates of

Variable	Estimate	SE	95% CI	p-value
FYs				
2021	0.020	0.003	[0.014, 0.025]	< 0.001 ***
2022	0.015	0.003	[0.010, 0.021]	< 0.001 ***
Sex				
M	0.000	0.008	[− 0.017, 0.017]	1.000
Age				
25–29	0.000	0.008	[− 0.017, 0.017]	1.000
30–34	0.163	0.008	[0.147, 0.180]	< 0.001 ***
35–39	0.124	0.008	[0.108, 0.141]	< 0.001 ***
40–44	0.208	0.008	[0.192, 0.225]	< 0.001 ***
45–49	0.217	0.008	[0.201, 0.234]	< 0.001 ***
50–54	0.195	0.008	[0.178, 0.212]	< 0.001 ***
55–59	0.190	0.008	[0.173, 0.206]	< 0.001 ***
60–64	0.205	0.008	[0.188, 0.221]	< 0.001 ***
65–69	0.213	0.008	[0.196, 0.229]	< 0.001 ***
70–74	0.222	0.008	[0.205, 0.239]	< 0.001 ***
75–79	0.231	0.008	[0.214, 0.247]	< 0.001 ***
80–84	0.237	0.008	[0.220, 0.254]	< 0.001 ***
85–89	0.247	0.008	[0.231, 0.264]	< 0.001 ***
≥ 90	0.271	0.008	[0.254, 0.288]	< 0.001 ***
Age·Sex				
M, 25–29	0.000	0.012	[− 0.023, 0.023]	1.000
M, 30–34	− 0.031	0.012	[− 0.054, − 0.007]	0.013 *
M, 35–39	− 0.002	0.012	[− 0.026, 0.022]	0.851
M, 40–44	− 0.049	0.012	[− 0.073, − 0.026]	< 0.001 ***
M, 45–49	− 0.057	0.012	[− 0.081, − 0.033]	< 0.001 ***
M, 50–54	− 0.037	0.012	[− 0.061, − 0.013]	0.003 **
M, 55–59	− 0.017	0.012	[− 0.041, 0.007]	0.152
M, 60–64	− 0.032	0.012	[− 0.056, − 0.008]	0.010 *
M, 65–69	− 0.030	0.012	[− 0.054, − 0.006]	0.015 *
M, 70–74	− 0.033	0.012	[− 0.057, − 0.009]	0.007 **
M, 75–79	− 0.032	0.012	[− 0.056, − 0.009]	0.009 **
M, 80–84	− 0.027	0.012	[− 0.051, − 0.003]	0.028 *
M, 85–89	− 0.026	0.012	[− 0.050, − 0.003]	0.031 *
M, ≥ 90	− 0.042	0.012	[− 0.065, − 0.018]	< 0.001 ***

Table 3. Risk factors for vascular access dysfunction recurrence within three months after the initial intervention. The intercept is omitted from the table. The reference categories were FY2020, Female sex, and an age group of 20–24 years. Model fit statistics: Adjusted $R^2 = 0.9813$ (F-statistic, $p < 0.001$). Significance codes: *** $p < 0.001$; ** $p < 0.01$; * $p < 0.05$. Estimates represent changes in vascular access dysfunction recurrence within 3 months of the initial intervention. Age and sex interaction terms represent the additional effect for males in each age group compared to females. The analysis was based on 90 aggregated observations (3 fiscal years × two sex categories × 15 age groups). Abbreviations: CI, confidence interval; FY, fiscal year; M, male.

VA dysfunction in female patients and older adults, with age-related effects showing distinct patterns based on sex (Tables 2, 3). The annual incidence rate of VA dysfunction rarte was estimated at 74.0% (SE: 1.7%) and VA recurrence rate was 16.9% (SE: 0.5%), consistent with the prevalence of VA complications reported in previous studies[12]. Despite the methodological limitations of the data source, our findings suggest that NDB Open Data can serve as a valuable resource for understanding the real-world prevalence of VA dysfunction in a large patient population.

The observed annual VA dysfunction rate of 74% was similar to that reported previously[12]. The treatment of VA dysfunction is a high-cost, single surgical procedure. Previous studies have suggested high reliability of claims data for such expensive surgical procedures[13]. These findings indicated the potential validity of the incidence rates observed in this study. However, several limitations affect our assessment of the incidence rates. First, these treatments are billed under the single procedure code "K616-4 Percutaneous Access Angioplasty/Thrombectomy," which prevents differentiation between planned angioplasty and emergency thrombectomy procedures. Including various types of interventions, such as VA dysfunction events, may lead to an overestimation of the true incidence rate. Additionally, the reimbursement system restricts claims to one procedure within 3 months of the initial intervention, likely resulting in an underestimation of the recurrence rate. The diverse

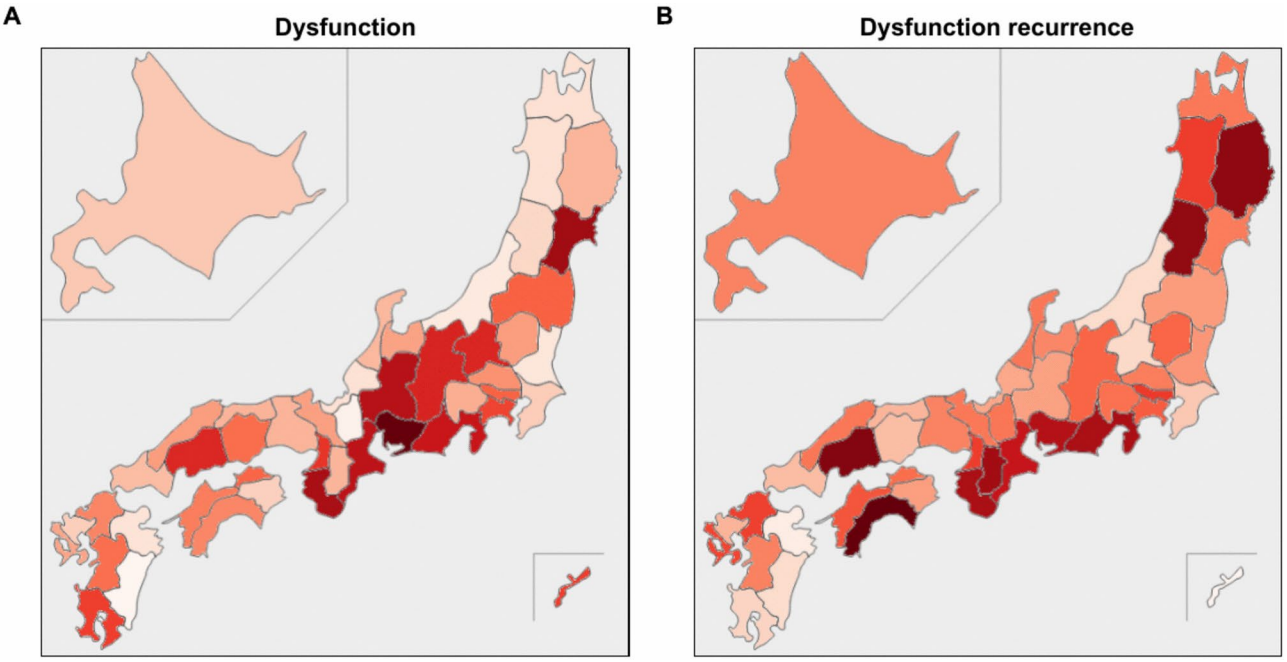

Fig. 2. Vascular access (VA) dysfunction rates and recurrence rates within three months after the initial intervention by prefecture. (**a**) VA dysfunction rate by prefecture. This panel shows the rate of VA dysfunction at initial incidence, calculated as the total number of VA dysfunction cases divided by the total number of patients with end-stage renal disease in each prefecture. (**b**) VA dysfunction recurrence rate within three months after the initial intervention (VA recurrence) by prefecture. This panel shows the recurrence rate of VA recurrence, calculated as the total number of VA recurrence divided by the total number of VA dysfunction cases in each prefecture. Both panels use color bars to represent percentage rates, with near-white representing the lowest values and dark red representing the highest. For initial incidence (**a**), the range is 30% to 90%. For recurrence rates (**b**), the range is 12% to 26%. Abbreviations: VA, vascular access; VA recurrence, VA dysfunction recurrence within three months after the initial intervention.

range of treatments for VA dysfunction-related complications highlights the need for further research to achieve a more accurate incidence assessment.

The estimated number of ESRD patients in Japan, derived from NDB Open Data, was 299,373 (SE: 499) (Table 1), which was approximately 14% lower than the values reported in the literature[3]. This discrepancy can be attributed to the following three factors. First, this study focused on ESRD patients who underwent VA procedures, excluding peritoneal dialysis patients, who account for approximately 3% of ESRD patients[14]. Second, the calculation of chronic maintenance dialysis management fees may have been inaccurate for patients receiving both inpatient treatment and outpatient care at the same facility within the same month[15]. Third, the characteristics of the NDB Open Data prevent it from capturing accounting for the approximately 10% of the crude mortality rate among Japanese dialysis patients[14]. Given these limitations, the estimated value provides a reasonable approximation of the total ESRD population.

Regarding the impact of sex and age on VA dysfunction, the results showed significantly higher rates in female patients and older adults (Fig. 1, Tables 2, 3). These findings are consistent with previous reports on sex and age-related patterns in VA dysfunction[16,17]. Notably, while the initial VA dysfunction incidence was significantly lower in young male patients than in their female counterparts ($p < 0.001$), this difference diminished with advancing age. For recurrence, both sexes exhibited age-related increases in recurrence rates; however, the rate of increase was more gradual in men than in women (Table 3). These sex and age-related differences were consistently confirmed through additional statistical analyses, demonstrating their stability over the three-year observation period (Tables 2, 3).

The observed sex- and age-related differences in VA dysfunction likely reflect multifaceted factors, including vascular structural and functional changes associated with aging, the influence of sex hormones, disparities in lifestyle-related diseases, and differences in healthcare access and treatment opportunities[18,19]. Specifically, the variation in sex differences in later life may result from sex-specific patterns of atherosclerosis progression, vascular changes following estrogen depletion in women, and age-related hormonal changes in men, such as reduced testosterone[18,19]. These findings underscore the need for personalized VA management strategies and highlight the importance of early intervention and preventive measures, particularly for high-risk groups. However, it should be noted that the findings of this study were based on aggregated data, limiting the ability to evaluate key factors such as VA type, location, comorbidities, and treatment patterns in individual patients[7,20]. These limitations suggest the need for caution when interpreting the observed associations between sex, age, and VA dysfunction.

Furthermore, this study revealed regional disparities in the VA dysfunction rate among ESRD patients in Japan (Fig. 2). Despite the country's high level of ethnic homogeneity (approximately 98% Japanese)[21], we observed significant regional variations (Fig. 2). Supplementary Figs. 1 and 2 also highlighted the differences in treatment strategies, such as stent placement and thrombectomy for VA dysfunction. These disparities likely reflect a combination of factors, including the distribution of medical resources, institutional criteria for managing VA dysfunction, socioeconomic conditions, and regional lifestyle differences. Further investigation of these regional disparities, considering both institutional and regional characteristics, is warranted.

Conclusion

In this study, analyses of the NDB Open Data Japan showed that VA dysfunction incidence in ESRD patients varies significantly by sex and age, with higher rates among females and older adults, suggesting sex-dependent aging effects. The observed regional variations likely reflect heterogeneity in dialysis care delivery systems across areas. These findings suggest the importance of considering sex-specific factors, age-related characteristics, and regional variations in VA dysfunction prevention and management. The application of real-world data in epidemiological research, as shown in this study, suggests the potential of such data to refine patient care protocols and inform clinical practice. However, the inherent limitations of NDB Open Data Japan necessitate cautious interpretation of our findings. Future prospective studies incorporating comprehensive clinical parameters are warranted to validate these observations and elucidate the mechanisms underlying VA dysfunction, ultimately facilitating evidence-based preventive measures.

Study limitations

This study had several important limitations. First, the use of the NDB Open Data, which provides only aggregated data stratified by age, sex, and region, precluded patient-level tracking and long-term follow-up [22]. This limitation made it impossible to evaluate key confounders, such as the type and location of the VA, comorbidities like hypertension and diabetes, and lifestyle factors such as alcohol consumption and smoking. Additionally, we could not assess outcomes such as patient mortality, VA abandonment, reconstruction, and patency rates, nor could we conduct survival analyses or patency calculations for AVF and AVG.

Second, the lack of detailed information on the nature and causes of VA dysfunction in the databases posed significant limitations. In Japan, while many VA interventions are performed as elective procedures for stenosis detected during routine surveillance, our database could not distinguish between such planned procedures and emergency interventions for acute complications. Additionally, we could not determine whether the dysfunction was acute or chronic in nature. Furthermore, owing to limitations in identifying dialysis-specific use, we excluded CVCs, which restricted the comprehensiveness of the evaluation of VA complications.

Third, reimbursement-related constraints affected the analysis. Changes in reimbursement policies after 2020 have made it difficult to differentiate between AVFs and AVGs, requiring us to treat these distinct access types as a single category. This limitation prevented a detailed analysis of dysfunction rates and treatment outcomes by access type. Additionally, reimbursement rules allowed claims for VA dysfunction treatment only once within 3 months of the initial intervention, potentially underestimating dysfunction rates during this period.

Finally, the regional analysis faced similar limitations. The study could not directly evaluate factors such as the size and specialization of medical institutions, the distribution of healthcare resources, or regional socioeconomic indicators. Consequently, identifying the specific factors underlying the observed regional disparities proved challenging.

Methods

Ethics statement

The NDB Open comprises anonymized open data, excluding individual patient information. Consequently, ethical approval and informed consent were not required.

Data source

This study employed datasets from NDB Open[11], particularly the seventh, eighth and ninth versions thereof. These datasets, sourced from the MHLW, spanned the fiscal years (FYs) of 2020 to 2022. The respective timeframes for these datasets were as follows: for FY 2020, from April 1, 2020 to March 31, 2021; for FY 2021, from April 1, 2021 to March 31, 2022 and for FY 2022, from April 1, 2022 to March 31, 2023.

Owing to reimbursement revisions related to treatments for VA dysfunction, items were subdivided after 2020; therefore, we conducted the analysis using data from that year onward. We created two types of datasets were created based on treatment: the first categorized by sex and a 5-year age groups, and the second by the 47 prefectures. In this study, we extracted data from the records of inpatients and outpatients with ESRD who had undergone VA dysfunction procedures.

Definition of ESRD

To estimate the total number of ESRD, we combined three billing categories: outpatient medical management fee for chronic maintenance dialysis (management fee for dialysis; billing code: 113002510), VA creation procedures (billing codes: 150416410, 150416510, 150151150, and 150151250), and artificial kidneys (AKs; billing code: J038). Based on these categories, we estimated the number of ESRD patients in both outpatient and inpatient settings and summed them to calculate the total number of ESRD patients. This study focused on evaluating the proportion of VA dysfunction in patients on HD, excluding emergency dialysis and peritoneal dialysis from the aggregation.

To estimate the number of outpatients with ESRD, we used the management fee for dialysis (cases/month) and the number of VA creation procedures (cases/year) (Eq. 1). The management fee for dialysis is a monthly reimbursement indicator for outpatient care of chronic maintenance dialysis patients and is not applicable during the first two months after dialysis initiation or during hospitalization. The number of VA creation procedures reflects the number of newly initiated dialysis patients, considering the usable lifespan of the VA. We adjusted for the gap in dialysis management fees during the first two months by multiplying the number of VA creation procedures by two. These procedures included both AVF and AVG.

$$ESRD\,(Outpatient) = \frac{Management\,fee\,for\,dialysis + 2 \times VA\,creation\,procedures}{12} \quad (1)$$

To estimate the number of inpatients with ESRD, we used the annual number of inpatient AK billing claims (cases/year) (Eq. 2). AK encompasses various dialysis modalities, including HD and hemodiafiltration, and represents the annual frequency of dialysis use among inpatients. For further details regarding AK, please refer to Supplementary Table 1. The estimated number of inpatients with ESRD was calculated by assuming that dialysis was performed three times per week and dividing the total annual dialysis sessions by the standard annual dialysis sessions per individual.

$$ESRD\,(Inpatient) = \frac{AK(Inpatient)}{365/7 \times 3} \quad (2)$$

Finally, we calculated the total number of ESRD patients by summing the outpatient and inpatient ESRD estimates (Eq. 3).

$$ESRD = ESRD\,(Outpatient) + ESRD\,(Inpatient) \quad (3)$$

Definition of VA dysfunction

We defined VA dysfunction as any instance where medical intervention was required to address a failure or complication of VA, as such dysfunction necessitates intervention. VA dysfunction encompasses various conditions, including thrombotic and non-thrombotic complications, acute and chronic issues, and functional problems such as flow limitations and elevated venous pressures. Based on medical billing codes[4,7] into two types: VA dysfunction and VA re-dysfunction. VA dysfunction included all treatment modalities, including thrombolysis, thrombectomy, stent graft placement, and VA reconstruction (Supplementary Table 2a,b). VA re-dysfunction was defined as follow-up interventions performed within 3 months of a preceding VA dysfunction intervention (Supplementary Table 2b). This period is based on reimbursement rules in the medical billing system.

We excluded CVCs because they are temporary VA devices, and their dysfunction is typically managed through replacement rather than treatment. These codes encompass both thrombotic and non-thrombotic complications requiring intervention in permanent VA but do not differentiate between acute and chronic complications. Additionally, they do not allow us to determine the reasons for interventions, such as thrombosis, infection, or other complications, whether initial or follow-up. Moreover, we could not distinguish between AVF and AVG due to changes in the medical billing system in 2020.

Estimation of VA dysfunction rate

To comprehensively evaluate the overall status of VA dysfunction, we defined two rates based on the previously described classifications of VA dysfunction interventions. The VA dysfunction incidence rate was calculated as the number of new VA-related interventions performed in each fiscal year, divided by the total number of ESRD patients (Eq. 3). The VA re-dysfunction incidence rate (previously termed "VA recurrence rate") was calculated as the number of new VA dysfunction interventions occurring within three months of an initial intervention, divided by the total number of initial interventions during the same period. These metrics both represent incidence rates, as they measure new events over a specific time period, rather than prevalence, which would indicate the proportion of existing cases in a population at a given point in time.

Statistical analyses

To comprehensively evaluate factors associated with the incidence and recurrence of VA dysfunction, we conducted the following statistical analyses. First, we performed a one-way ANOVA[23] to evaluate age dependency in the incidence rate of VA dysfunction across age groups. Second, to comprehensively investigate factors influencing the recurrence of VA dysfunction, we conducted multiple regression analysis[24]. In the regression model, the recurrence rate of VA dysfunction was set as the dependent variable, while FY, sex, and age group were included as independent variables. FY 2020, female sex, and the 20–24 age group, which exhibited the most stable vascular function, were used as reference categories. Age groups were categorized in 5-year intervals. Additionally, to assess sex-specific age effects, we included an interaction term between age group and sex in the model.

As a supplementary analysis, we investigated the association between age groups and the incidence rate of VA dysfunction using Spearman's rank correlation coefficient for each sex. To compare these Spearman's correlation coefficients between fiscal years, we applied Fisher's z-transformation[26]. We also used the Mantel–Haenszel test[25] to evaluate sex differences in VA dysfunction rates. To examine regional variations by prefecture, we employed hierarchical clustering[27] and local Moran's I statistic[28] to identify geographic clusters and evaluate the geographic heterogeneity in the incidence of VA dysfunction. Details of the regional analysis methodology are provided in Supplementary Methods.

We conducted all statistical analyses using the R and Python programming languages. We applied a statistical significance level of 0.05, except for the exploratory analysis with local Moran's I, where a threshold of 0.1 was used as per convention[29].

Data availability

The seventh, eighth and ninth versions of the NDB Open Data can be downloaded from the MHLW website at the following URL: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0,000,177,182.html, which was accessed on August 1, 2024.

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Author contributions

Conceptualization: K. T. S. and K. N. Methodology: K. T. S. Software: K. T. S. Writing—original draft preparation: K. T. S. Writing—review and editing: K. T. S., K. N., and Y. S. Project administration: Y. S. All authors have read the final version of the manuscript and have agreed to publication thereof.

Declarations

Competing interests

The authors declare no competing interests.

Ethical approval
The NDB Open Data is open to the public through the MHLW, and does not require ethical approval for the use thereof.

Informed consent
The requirement for patient consent was waived, because the NDB Open Data comprises anonymized open data and does not include individual patient information.

Additional information
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