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Nationwide Survey of Post-Transplant Glomerular Diseases, Based on the Japan Renal Biopsy Registry (J-RBR)

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Background: Nationwide data on allograft kidney biopsies have been limited in number, in contrast to the large amount of accumulated data on native kidney biopsies. In this context, we have surveyed transplant biopsy data based on the nationwide database, the Japan Renal Biopsy Registry (J-RBR).

Material/Methods: A total of 2430 transplant biopsy cases were registered in the web-based J-RBR from January 2007 to January 2018. We categorized the entries regarding both the purpose of the biopsy and pathological diagnosis, and confirmed transplant glomerular diseases based on the clinical and pathological diagnosis.

Results: Of the 2430 total transplant biopsy cases, 637 cases, including 9 cases of baseline biopsy, 216 cases of protocol biopsy, and 232 cases of episode biopsy, had a pathological diagnosis, including glomerular diseases, rejection, calcineurin inhibitor nephropathy, and interstitial fibrosis and tubular atrophy. Of these, 127 cases presented with glomerular disease, including 8 cases of baseline biopsy, 23 of protocol biopsy, 59 of episode biopsy, and 37 of unknown purpose). A total of 127 biopsies with glomerular disease revealed a high prevalence of immunoglobulin A nephropathy (n=38, 29.9%), followed by mesangial proliferative glomerulonephritis (n=29, 22.8%) and focal segmental glomerulosclerosis (n=8, 6.3%) when focused on protocol and episode biopsies.

Conclusions: The nationwide transplant biopsy database demonstrated the pathological characteristics of 637 cases, including 127 cases of post-transplant glomerular disease. The protocol and episode biopsies included high prevalence rates of IgAN, followed by FSGS.

Keywords: **Glomerulonephritis, IGA • Kidney Transplantation • Pathology**

Abbreviations: **ANCA** – anti-neutrophil cytoplasmic antibody; **CNI** – calcineurin inhibitor; **DN** – diabetic nephropathy; **ESKD** – end-stage kidney disease; **FSGS** – focal segmental glomerulosclerosis; **IF/TA** – interstitial fibrosis and tubular atrophy; **IgAN** – immunoglobulin A nephropathy; **J-RBR** – the Japan Renal Biopsy Registry; **MesPGN** – mesangial proliferative glomerulonephritis; **MGN** – membranous glomerulonephritis; **MPGN** – membranoproliferative glomerulonephritis; **MPO** – Myeloperoxidase; **PR3** – Proteinase 3

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Background

Post-transplant glomerular disease has a strong impact on kidney allograft failure and long-term graft survival. Glomerular disease accounts for about 30% of end-stage kidney disease (ESKD), and its recurrence after transplantation leads to a decline in kidney allograft function and graft loss [1]. The post-transplant glomerular diseases identified included various characteristics, including not only recurrent glomerular disease but also transmitted glomerular disease and *de novo* glomerular disease. Data on the frequency and prognosis of post-transplant glomerular disease have been accumulated and have been reported for each type of glomerular disease, such as immunoglobulin A nephropathy (IgAN), focal segmental glomerulosclerosis (FSGS), and membranoproliferative glomerulonephritis (MPGN). In Japan, however, the data on post-transplant glomerular disease have been limited to single-center experiences, and nationwide data have never been collected before. In this context, we herein report the incidence and characteristics of post-transplant glomerular disease, based on the Japan Renal Biopsy Registry (J-RBR) [2].

Material and Methods

Entries Based on the J-RBR

We analyzed transplant biopsy data from all over the country based on the J-RBR, which was launched in 2007 by the Committee for the Standardization of Renal Pathological Diagnosis and the Committee for the Kidney Disease Registry of the Japanese Society of Nephrology. It is a nationwide, web-based, and prospective registry system in Japan [2]. The registry includes patient data on the clinical diagnosis, histological diagnosis based on the pathogenesis, and histological diagnosis based on a histopathological examination with additional information. The pathological diagnosis was made by nephrologists, nephropathologists, and pathologists, depending on each institution. The J-RBR appears in the Clinical Trial Registry of UMIN (registration number UMIN 00000618), and the Ethics Review Board of the Japanese Society of Nephrology and each research institution approved the study in accordance with the Declaration of Helsinki (The University of Tsukuba Hospital, No. H20-330). Written informed consent was obtained from all the patients who participated in the J-RBR. In the present sub-study, we surveyed all entries from January 2007 to January 2018 and selected cases with kidney allograft biopsy. The present sub-study was approved by the Ethics Review Board of the University of Tsukuba Hospital (No. H30-253).

The Diagnostic Classification of the J-RBR

In the J-RBR, clinical diagnoses were divided into these categories: acute nephritic syndrome, rapidly progressive nephritic

syndrome, recurrent or persistent hematuria, chronic nephritic syndrome, nephrotic syndrome, renal disorder with metabolic disorder, renal disorder with collagen disease or vasculitis, hypertensive nephropathy, inherited renal disease, acute renal failure, drug-induced nephropathy, renal transplantation, congenital renal urinary tract abnormalities, polycystic kidney disease, hemolytic uremic syndrome/thrombotic thrombocytopenic purpura, and others. Next, the histological diagnoses based on the pathogenesis were classified into categories, including primary glomerular disease except IgAN, IgAN, purpura nephritis, lupus nephritis, Myeloperoxidase (MPO)-anti-neutrophil cytoplasmic antibody (ANCA)-positive nephritis, Proteinase 3 (PR3)-ANCA-positive nephritis, anti-glomerular basement membrane antibody nephritis, hypertensive nephrosclerosis, thrombotic microangiopathy, diabetic nephropathy (DN), amyloid nephropathy, Alport syndrome, thin basement membrane disease, infection-related nephropathy, transplanted kidney, and others. Finally, histological diagnoses based on a histopathological examination were divided into these categories: minor glomerular abnormalities, FSGS, membranous glomerulonephritis (MGN), mesangial proliferative glomerulonephritis (MesPGN), endocapillary proliferative glomerulonephritis, MPGN types I and III, dense deposit disease, crescentic and necrotizing glomerulonephritis, sclerosing glomerulonephritis, nephrosclerosis, acute interstitial nephritis, chronic interstitial nephritis, acute tubular necrosis, transplanted kidney, and others.

Clinicopathological Parameters and Statistics

Other than the clinical diagnosis, histological diagnosis based on the pathogenesis, and histological diagnosis based on histopathological examination, each patient's data contained additional information, including the timing and reason for the biopsy and the pathological findings. Information on the timing and reason for the transplant biopsy was divided into baseline, protocol, and episode, on the basis of additional comments in questionnaires from each institution. Baseline biopsies included both time-zero and 1-hour post-reperfusion biopsies. The timing of the protocol biopsies varied depending on the institution. Episode biopsies included cases such as elevation of serum creatinine, proteinuria and hematuria. Cases without any information on the timing of the transplantation were categorized as unknown. As for pathological findings, we focused on 4 categories, namely glomerular diseases, rejection, calcineurin inhibitor (CNI) nephropathy, and interstitial fibrosis and tubular atrophy (IF/TA), as representative. Duplicates were allowed in these pathological findings. Data on age and creatinine are presented as means \pm standard deviation.

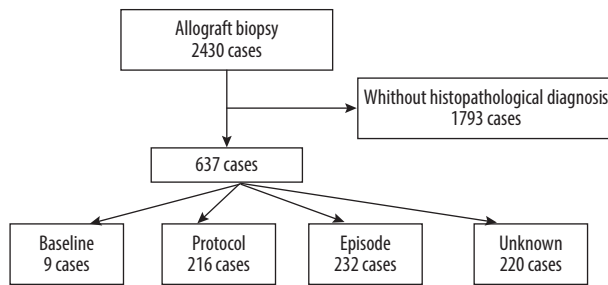


Figure 1. Entry number of the study on renal allograft biopsies of Japan Renal Biopsy Registry.

Table 1. Clinicopathological characteristics of renal allograft biopsies.

		Baseline	Protocol	Episode	Unknown	Total
Number	(n)	9	216	232	220	637
Age	(Average±SD years)	45.8±20.0	43.5±13.6	42.3±14.5	38.4±16.9	41.3±15.4
Sex	(Male: Female)	6:3	102:74	162:70	133:87	403:234
Urinary protein	–	7	73	75	111	266
	±	0	66	45	37	148
	1+	1	30	70	35	136
	2+	1	3	27	22	53
	3+	0	4	14	10	28
	4+	0	0	1	5	6
Hematuria	–	7	125	130	133	395
	±	1	16	27	26	70
	1+	1	14	17	15	47
	2+	0	9	36	18	63
	3+	0	12	22	28	62
Serum creatinine	(Average±SD mg/dL)	7.8±3.7	1.4±0.3	2.5±2.0	2.3±2.0	2.2±1.9
Pathological diagnosis	Glomerular disease	8	23	59	37	127
	Rejection	0	56	114	65	235
	CNI nephropathy	0	14	42	24	80
	IF/TA	0	10	5	29	44

CNI – calcineurin inhibitors, IF/TA – interstitial fibrosis and tubular atrophy.

Results

Diagnosis and Classification in all 2430 Cases

A total of 2430 cases, categorized as “transplanted kidney” cases in the histological diagnosis based on the pathogenesis, were selected for this investigation on kidney allograft biopsy. As for the clinical diagnoses, 2379 cases were categorized as renal transplantations, 4 cases as acute nephritic syndrome, 3 cases as rapidly progressive nephritic syndrome, 36 as chronic nephritic syndrome (of these 36 cases, 23 cases were also labeled as renal transplantation), 5 cases as nephrotic syndrome, 1 case as renal disorder with metabolic disorder, 2 cases as hypertensive

nephropathy, 1 case as inherited renal disease, 1 case as acute renal failure, 1 case as drug-induced nephropathy, 11 cases as congenital renal urinary tract abnormalities, and 9 cases as others.

As for the histological diagnoses based on a histopathological examination, 2356 cases were transplanted kidney cases, followed by 8 cases of minor glomerular abnormalities, 1 of FSGS, 2 of MGN, 3 of MesPGN, 1 of endocapillary proliferative glomerulonephritis, 3 of MPGN (types I and III), 1 of dense deposit disease, 1 of crescentic and necrotizing glomerulonephritis, 1 of sclerosing glomerulonephritis, 5 of acute interstitial nephritis, 4 of chronic interstitial nephritis, 9 of acute tubular necrosis, and 35 others.

Table 2. Pathological diagnosis in biopsy-proven glomerular diseases.

	Baseline				Protocol			
	Transmission	Recurrence	Unknown	Total	Transmission	Recurrence	Unknown	Total
IgAN	4	0	2	6	1	5	8	14
FSGS	0	0	0	0	0	1	1	2
MGN	1	0	0	1	0	0	0	0
MPGN	0	0	0	0	0	0	0	0
MesPGN	0	0	0	0	0	1	5	6
DN	0	0	0	0	0	0	0	0
Others	0	0	1	1	0	1	0	1
Total	5	0	3	8	1	8	14	23
	Episode				Unknown			
	Transmission	Recurrence	Unknown	Total	Transmission	Recurrence	Unknown	Total
IgAN	1	21	2	24	0	20	1	21
FSGS	0	3	3	6	0	2	3	5
MGN	0	0	0	0	0	1	1	2
MPGN	0	0	1	1	0	0	2	2
MesPGN	0	1	22	23	0	0	2	2
DN	0	0	1	1	1	0	1	2
Others	0	0	4	4	0	2	1	3
Total	1	25	33	59	1	25	11	37

IgAN – immunoglobulin A nephropathy; FSGS – focal segmental glomerulosclerosis; MGN – membranous glomerulonephritis; MPGN – membranoproliferative glomerulonephritis; MesPGN – mesangial proliferative glomerulonephritis; DN – diabetic nephropathy.

Transplant Biopsy with Histopathological Findings

Of the 2430 total transplant biopsy cases, 1793 cases were excluded from the present investigation because they were lacking a pathological diagnosis (Figure 1). The remaining 637 cases included 9 cases of baseline biopsy, 216 cases of protocol biopsy, 232 cases of episode biopsy, and 220 cases with an unknown cause for the biopsy. Of these 637 cases, post-transplant glomerular disease was diagnosed in 127 cases.

Clinical Characteristics of Renal Allograft Biopsies

Table 1 shows the clinical characteristics of the renal allograft biopsies, including age, sex, urinary protein level, hematuria, serum creatinine, and histopathological diagnosis, represented as glomerulonephritis, rejection, CNH nephropathy, and IF/TA. In 637 cases, the age on average was 41.3 ± 15.4 , with 403 males and 234 females; 223 cases presented with proteinuria (more than 1+) and 172 cases with hematuria (more than 1+). The serum creatinine level was 2.2 ± 1.9 mg/dL in total, 7.8 ± 3.7 mg/dL in baseline, 1.4 ± 0.3 mg/dL in protocol, 2.5 ± 2.0 mg/dL in episode, and 2.3 ± 2.0 mg/dL in unknown cause. As for the histopathological diagnoses, glomerular disease was found in 127 cases, rejection in 235 cases, CNH nephropathy in 80 cases, and

IF/TA in 44 cases. Of the 127 cases of glomerular disease, 8 were in baseline, 23 in protocol, 59 in episode, and 37 in unknown cause, respectively.

Post-transplant Glomerular Disease

The histopathological diagnoses in cases of biopsy-proven glomerular disease were divided into IgAN, FSGS, MGN, MPGN, MesPGN, DN, and others (Table 2). The cases were also classified into transmission, recurrence, and unknown for each type of biopsy. Even though none of the cases were clearly described as *de novo* glomerular disease, “unknown” cases may also include *de novo* glomerular diseases.

A total of 127 biopsies with glomerular disease revealed a high prevalence of IgAN (n=65, 51.2%), followed by MesPGN (n=31, 24.4%) and FSGS (n=13, 10.2%). The number of baseline biopsies was limited, but these biopsies showed a high prevalence of transmission of IgAN from donors compared to other glomerular diseases. In protocol and episode biopsies, the prevalence was the highest for IgAN, with 38 cases (29.9%), 14 in protocol biopsies and 24 in episode, followed by MesPGN, with 29 cases (22.8%), 6 in protocol and 23 in episode, and FSGS, with 8 cases (6.3%), 2 in protocol and 6 in episode.

Table 3. Characteristics of post-transplant glomerular diseases obtained from nationwide survey.

		Hariharan 1999	Chailimpa- montree 2009	An 2012	Allen 2017	Present study 2019
Country		USA	Canada	Korea	Australia & NZ	Japan
Number of renal transplants	(n)	4913	2026	764	17 549	2 430
Pre-transplant glomerular disease (Biopsy-proven)	(n, %)					
	Total	NA	734	195	6 597	NA
	IgAN	NA	246, 33.5	129, 66.2	2501, 37.9	NA
	FSGS	NA	196, 26.7	16, 8.2	1403, 21.3	NA
	MGN	NA	20, 2.7	4, 2.1	357, 5.4	NA
	MPGN	NA	42, 5.7	8, 4.1	376, 5.7	NA
Post-transplant glomerular disease (Biopsy-proven)	(n, %)					
	Total	167	94	70	NA	127
	IgAN	22, 13.2	45, 47.9	54, 77.1	NA	38, 29.9
	FSGS	57, 34.1	30, 31.9	8, 11.4	NA	8, 6.3
	MGN	16, 9.6	6, 6.4	2, 2.9	NA	0, 0.0
	MPGN	18, 10.8	5, 5.3	3, 4.3	NA	1, 0.8
Recurrence of glomerular disease	(n, %)					
	Total	NA	68	NA	553	33
	IgAN	NA	38, 55.9	NA	225, 40.7	26, 78.8
	FSGS	NA	19, 27.9	NA	144, 26.1	4, 12.1
	MGN	NA	2, 2.9	NA	49, 8.9	0, 0.0
	MPGN	NA	2, 2.9	NA	61, 11.0	0, 0.0

USA – United States of America; NZ – New Zealand; NA – not available; IgAN – immunoglobulin A nephropathy; FSGS – focal segmental glomerulosclerosis; MGN – membranous glomerulonephritis; MPGN – membranoproliferative glomerulonephritis.

The number of cases of IgAN recurrence was 5 in protocol and 21 in episode, accounting for the highest number compared to other glomerular diseases. In addition, MesPGN cases may include IgAN, suggesting that the number of recurrent IgAN cases may have actually been higher. Combining the cases from protocol, episode, and unknown, excluding baseline cases, the number of recurrence cases was 46 for IgAN, 6 for FSGS, 1 for MGN, 0 for MPGN, 2 for MesPGN, and 0 for DN. In addition, as described above, most of the MesPGN cases were presumed to be IgAN.

Discussion

Graft survival has improved year by year, and after 2010, the graft survival rate was 98.7% at 1 year and 94.3% at 5 years for living donor transplants and 96.7% at 1 year and 88.0% at 5 years for deceased donor transplants in Japan (<http://www.asas.or.jp/jst/pdf/factbook/factbook2018.pdf>). These improvements owe much to the improvement in immunosuppressants;

in other words, the impact of recurrent glomerular disease on graft survival has been increasing over recent years. El-Zoghby et al reported that glomerular disease accounted for 36.6% of cases of graft loss [3]. Among the different types of glomerular disease, IgAN and FSGS are known to have high recurrence rates of almost 30-60% [4].

Nationwide data on post-transplant glomerular disease are limited, but 4 studies referred to its prevalence, shown in **Table 3** [1,5-7]. The number of allograft kidney biopsy, the prevalence of pre- and post-transplant glomerular disease, and the recurrence rate of glomerular disease were all addressed in these studies. In the present study, there was a total of 127 cases of post-transplant glomerular disease, including 38 cases (29.9%) of IgAN and 8 cases (6.3%) of FSGS when focused on protocol and episode biopsies, excluding the baseline and unknown categories. As for the recurrence of glomerular diseases, there were 33 cases in protocol and episode biopsies, including 26 cases (78.8%) of IgAN and 4 cases (12.1%) of FSGS. In the data from countries other than Japan, either

post-transplant glomerular disease or the recurrence of glomerular disease or both were given, with IgAN showing the highest number of cases followed by FSGS in most of these studies, except for a survey from the USA. These findings were similar to those of the present study.

Some risk factors have been reported for the development of recurrent glomerular diseases. For example, in recurrent IgAN, young age, male sex, a rapidly progressive course of the original disease before transplantation, the presence of specific HLA genotypes, no HLA mismatch, and high serum IgA levels have been reported to be risk factors [8-10]. For FSGS, recurrent risk factors include young age, rapid progression to ESKD, bilateral nephrectomy, White race, and loss of a previous allograft due to FSGS recurrence [11,12]. Preventive measures, represented as perioperative rituximab and therapeutic plasma exchange, have been studied, but post-transplant recurrence of FSGS remains unresolved.

In the present study, even though the total number was limited when focused on glomerular disease, the high prevalence rates of IgAN and FSGS showed the same trend as in previous studies. In addition, MesPGN in this study might include IgAN, suggesting the possibility that there were more cases of recurrent IgAN. Considering the fact that the prevalence of IgAN is higher in Eastern Asian countries than in North America or European countries, further studies from Japan may help achieve a better allograft prognosis. The present study has 3 limitations. First, the timing of the baseline and protocol biopsies were different depending on the institution. For example, the baseline biopsies included both 0-hour and 1-hour biopsies. Second, the registry form was not fully established

for accumulating allograft biopsy data, resulting in there being limited information on the timing of the biopsies and the clinical course. However, the registry was renewed in 2018 and the current system is now suitable not only for native kidney biopsies but also for allograft biopsies. We are aiming to analyze these newly accumulated data with our present data in the near future. Third, the diagnostic ability varied across institutions, which caused difficulties in integrating the information. Our future task is to close diagnostic gaps among institutions and to standardize pathological diagnosis.

Conclusions

The present study is the first to show the whole picture of transplant kidney biopsy in Japan. Nationwide renal transplant data are limited even in other countries, suggesting the importance of accumulating integrated data. This registry is ongoing with more specific data on kidney transplantation, and further studies with more detailed information are needed, with the goals of tackling the recurrence of glomerular disease and attaining better graft survival.

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Conflict of interest

None.

Appendix

The following investigators and initial institutions have participated in the development of the J-RBR since 2007: Hirofumi Makino and Hitoshi Sugiyama (Okayama University), *late* Takashi Taguchi (Nagasaki University), Hitoshi Yokoyama (Kanazawa Medical University), Hiroshi Sato (Tohoku University), Takao Saito (Fukuoka University; present institution: Sanko Clinic), Yoshie Sasatomi (Fukuoka University; present institution: Saiseikai Fukuoka General Hospital), Yukimasa Kohda (Kumamoto University; present institution: Hikinomori Clinic), Shinichi Nishi (Niigata University; present institution: Kobe University), Kazuhiko Tsuruya (Kyushu University; present institution: Nara Medical University), Yutaka Kiyohara (Kyushu University; present institution: Hisayama Research Institute For Lifestyle Diseases), Hideyasu Kiyomoto (Kagawa University; present institution: Tohoku Medical Megabank Organization, Tohoku University), Hiroyuki Iida (Toyama Prefectural Central Hospital; present institution: Toyama Prefectural Rehabilitation

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