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The German Transplantation Registry Reveals Deficiencies in the Listing Process for Kidney Transplantation

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Introduction: The time from dialysis onset to enrollment on the kidney waiting list (listing time) is a crucial step on the path to receiving a kidney allograft; however, this process has received very little research attention in the Eurotransplant (ET) area.

Methods: We retrospectively analyzed data from the German transplantation registry, including patients who were on the waiting list for a first kidney transplant in Germany between 2006 and 2016. Listing time was evaluated using a mixed linear model. The outcomes on the kidney waiting list were assessed using competing risk analyses.

Results: We assessed a total of 43,955 patients. Listing occurred at a higher pace in patients receiving living donor transplantations (median 0.4 years from dialysis onset) than in deceased donor transplantations (Eurotransplant Kidney Allocation System [ETKAS] 1.1 years, European Senior Program [ESP] 1.4 years, Acceptable Mismatch program 1.3 years), with 28.5% of living donor transplantations performed preemptively. There was only modest variation in listing time between the transplant centers. Patients with a history of viral infection, high immunization; hemodialysis patients; and patients with a higher body mass index (BMI) had a delayed listing process. Two of 3 patients listed in the ETKAS, excluding those with potential bonus points (pediatric, other organ transplantations), were eventually transplanted. Older patients, male patients, patients with blood type O, and patients with diabetic nephropathy as the underlying renal disease had the highest risk not to proceed to transplantation.

Conclusion: Although long waiting times remain the biggest hurdle for transplantation in Germany, there is ample room for improvement of the listing process.

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KEYWORDS: allocation; kidney transplantation; listing time; waiting list; Eurotransplant; German transplantation registry

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In 2022, approximately 4200 kidneys were allocated in the ET area, one of the largest organ exchange organizations in the world.[1] The time spent on dialysis, also referred to as 'waiting time,' is a crucial factor for kidney allocation within the ET area; however, patients may receive an organ offer with a shorter waiting time under certain circumstances, such as living donor transplantation, full house human leukocyte antigens [HLA] matches (0 mismatches of HLA-A, HLA-B or HLA-DR), and rescue allocation.[2] The listing time is the time it takes from dialysis onset to enrollment on the kidney waiting list and does not directly affect transplantation chances through the allocation algorithm; however, because only patients on the ET kidney waiting list are eligible for organ offers, each day spent off the list represents a missed opportunity for timely transplantation. The precise number of patients with end-stage renal disease in Germany is unknown because of a lack of a comprehensive registry and varies depending on the source. However, in 2006 there were at least 63,000[3] patients with end-stage renal disease with statutory health insurance on dialysis, of which 8473[4] had been listed for kidney transplantation, and by 2016 this number had increased (at least 93,000[5]), whereas the relative proportion of listed

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patients had decreased ($n = 7876$[6]). Despite the significance of listing in the transplantation process, there is a lack of comprehensive large-scale longitudinal assessments. The German transplantation registry, which includes transplantation-related and listing-related data of German patients on the ET kidney waiting list, has recently been launched.[7] This study was the first systematic analysis of the currently available German transplantation registry data, and included all patients on the kidney waiting list between 2006 and 2016. This study addressed the following crucial questions about the listing process:

1. What was the timeframe for enlisting patients who underwent kidney transplantation in different allocation programs?
2. Did significant variations exist in the duration of the listing process among transplant centers in Germany?
3. What were the outcomes of the listing process and which factors were associated with undesirable outcomes?

METHODS

We conducted a longitudinal, retrospective analysis of the German transplantation registry, encompassing information on the kidney transplant waiting list and transplantations during the specified timeframe. Ethics committee approval was not required for this study according to the German rules and regulations.

Data Source

The German Federal parliament determined that there should be a national transplantation registry to better capture the full transplantation process (*Gesetz zur Einrichtung eines Transplantationsregisters*, November 2016). In 2021, data from the years 2006 to 2016 was made available to researchers upon reasonable request to the German transplantation registry (https://transplantations-register.de/). The registry contains information such as baseline characteristics, donor characteristics, transplant data (e.g., donor type and ischemia time) and more. We accessed the data, which had been provided to the transplantation registry ET and Deutsche Stiftung Organspende (freeze date December 31, 2016) and used the following sub-elements: element_empfaenger, element_empfaenger_dringlichkeit, element_empfaenger_virologie, element_empfaenger_immunologie, element_followup_niere_medikation, element_organ_entnahme_niere, element_spender_lebend, element_spender_postmortem, element_transplantation, element_warteliste_niere.

Study Population

Our analysis included 43,955 individuals who had been listed on the kidney waiting list for the first time and were on the list between 2006 and 2016. The cohort also included patients who had been placed on the list at an earlier time, as long as they were still on the list during the specified period. The baseline characteristics of the cohort are provided online in the Supplementary Material (Supplementary Table S1). Subgroups of the cohort were used to investigate specific research questions, as indicated in the flow chart (Supplementary Figure S1).

End Points

The endpoint "listing time" was defined as the time from onset of dialysis to the patient's enlistment on the kidney waiting list. The endpoint of the competing risk analysis was a composite of "any-cause death" and "permanent removal from the kidney waiting list." The event "transplantation" was considered as a competing event.

Statistical Methods

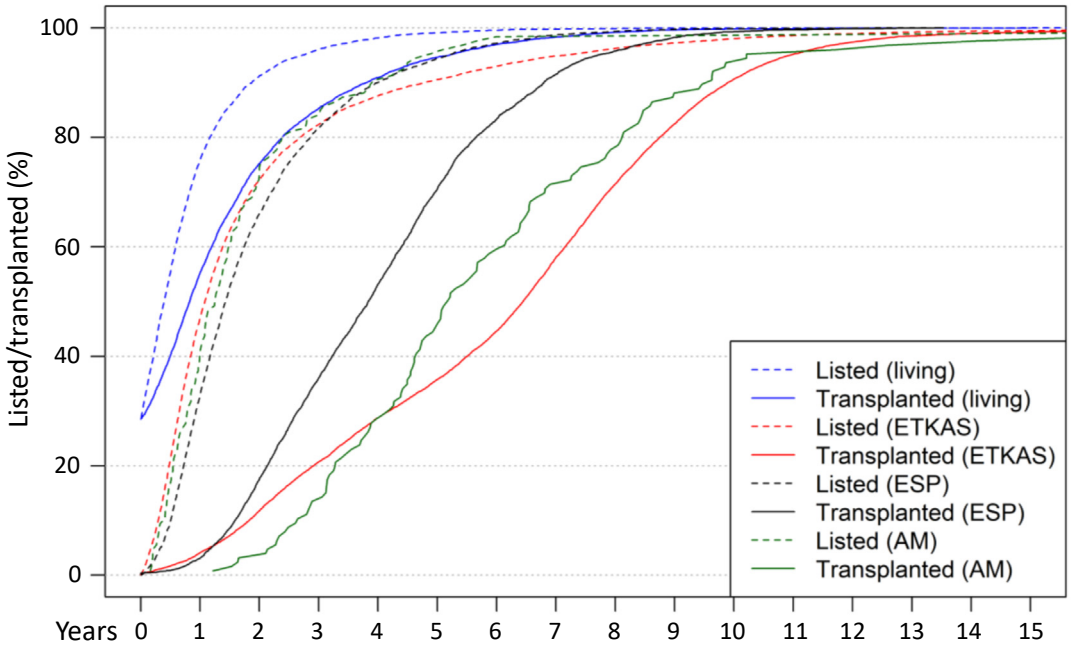
The output elements of the German transplantation registry were merged using the "tidyverse" package of R Studio (version 4.3; Posit PBC).[8] Graphs were created using base R and ggplot.[9] Survival analyses, linear mixed effects models, and generalized linear models were calculated using base R functions and the "lme4," "lmerTest," "survival," and "tidycmprsk" packages.[10-13] We used Kruskal-Wallis test to compare the median listing times of the transplant centers and Spearman's rho to assess a correlation between larger center size and listing times. A multivariate linear mixed model with listing time as the endpoint was employed after visually confirming that the model-specific assumptions were met for all covariates. Competing risk analysis with cumulative incidence curves for either "removal from list" or "death on list" was performed with "transplantation" considered as the competing event in the subset of patients on dialysis aged 18 to 64 years, excluding patients with other organ transplantations or panel reactive antibody (PRA) levels >85%. For the same subset of patients, multivariate Fine-Gray proportional subdistribution hazards regression adjusted for multiple covariates (as indicated) was performed to calculate hazard ratio (HRs). For survival analyses, patients were censored at the last day of follow-up. P-values < 0.05 were considered statistically significant.

RESULTS

Analysis of Listing Times Preceding Kidney Transplantation

To analyze the listing times preceding kidney transplantations, we included 24,150 patients who had

a **Listing and TX status since dialysis initiation (graft recipients 2006 - 2016)**



	(t -1)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Not listed (living)	6389	1542	559	250	118	58	29	14	8	3	3	3	2	2	2	2
Not transplanted (living)	6389	2866	1584	941	580	342	192	109	51	24	12	10	4	2	2	2
Not listed (ETKAS)	13210	7007	3667	2332	1641	1245	922	676	496	359	261	186	141	102	80	68
Not transplanted (ETKAS)	13210	12673	11661	10482	9413	8487	7320	5545	3771	2318	1236	635	342	196	133	99
Not listed (ESP)	4426	2977	1503	806	440	250	125	54	29	12	6	4	3	1	0	0
Not transplanted (ESP)	4426	4289	3653	2833	2074	1304	739	376	188	77	31	15	5	2	0	0
Not listed (AM)	126	75	33	21	12	6	2	2	2	2	2	2	2	2	2	2
Not transplanted (AM)	126	126	122	109	90	69	51	36	28	15	8	6	5	4	4	3

b **Proportion of preemptive living donor transplantations**

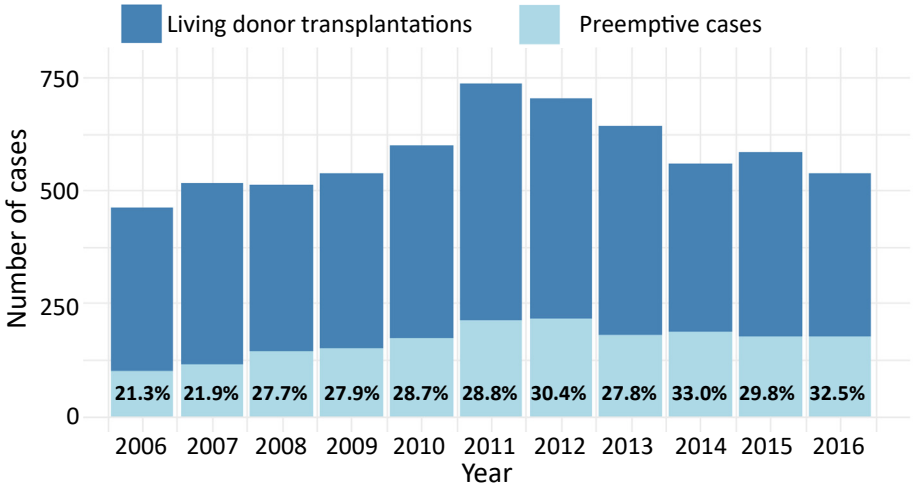


Figure 1. Listing times of patients with a first-time kidney transplantation in Germany between 2006 and 2016. (a) Listing and transplantation status after dialysis initiation for patients transplanted through various Eurotransplant allocation programs. (t-1) indicates at risk number before first day of listing. (n = 24,150) (b) Number of living donor kidney transplantations per year with the proportion of preemptively transplanted organs indicated in light blue. AM, acceptable mismatch; ETKAS, Eurotransplant Kidney Allocation System; TX, transplantation.

undergone first-time kidney transplantations. Preemptive transplantation is no longer possible in deceased donor transplantation in the ET area; and thus, for better comparability with the current situation, preemptively transplanted patients in deceased donor programs were excluded from this analysis (Supplementary Figure S1). A total of 6389 (26.7%) patients received living donor organs, whereas 13,210 (54.7%), 4426 (18.3%), and 126 (5.0%) patients received transplants through the ETKAS, ESP, and Acceptable Mismatch program, respectively. There were substantial program-specific differences in the time it took to enlist the patients (Figure 1). Living donor recipients were listed much sooner after initiating dialysis compared to the patients in deceased donor programs, with 28.7% of patients listed preemptively and 28.5% transplanted preemptively. Median listing and transplantation times were 0.4 years and 0.8 years for living donor transplantation, 1.1 years and 6.4 years for the ETKAS, 1.4 years and 3.8 years for the ESP, and 1.3 years and 5.2 years for the Acceptable Mismatch program, respectively. To get an impression of the benefit of early listing, we analyzed data of deceased donor kidney recipients listed during the first year after dialysis. After excluding the patients transplanted with potential ETKAS bonus points (pediatric and other organ transplantations), we identified 6598 patients, including 282 (4.3%) who were transplanted within the first year after dialysis initiation. Rescue allocation accounted for 22.0% of these transplantations as compared to only 10.4% for patients who were listed in the first year but transplanted later on, and more patients transplanted in the first year had been allocated through the ESP program (43.6% vs. 21.1%; Supplementary Table S2). Transplantations within the first year occurred evenly across centers (Supplementary Table S3).

Factors Associated With Listing Times

We assessed listing times in centers that had performed at least 250 transplantations during the study period. The number of listings per center in the study period ranged from 401 to 4368 listings (Supplementary Table S3). The listing times did not vary strongly between centers, because the median listing times were relatively consistent across centers, with none falling outside the 25th and 75th percentiles of the cohort (Figure 2). The Spearman correlation (−0.05) between center size and the listing time was very weak. In addition, we evaluated further factors associated with listing times in all patients who were on dialysis when entering the kidney waiting list ($n = 37{,}811$). In a mixed effects model for linear regression, we employed "listing centers" and "planned living donor transplantation" as higher hierarchical levels (random effects) and evaluated influences on the listing times of additional variables (fixed effects; Table 1). With an intraclass coefficient of 0.017, the total variance explained by the "listing center" variable was very low at 1.7%, whereas the variance explained by "planned living donor transplantation" at 8.5% was higher (intraclass coefficient 0.085). Factors associated with longer listing times were PRA (+81.5 days for PRAs >5%–≤85%, and +234.7 days for PRAs >85%), a history of HIV or viral hepatitis (+278.4 days), a high BMI (+5.7 days per unit), and blood type AB (+55.4 days compared to blood type A). A higher age (−3.4 days per year), peritoneal dialysis (−164.9 days compared to hemodialysis), blood type O (−16.4 days compared to blood type A), other organ transplantation (−212.8 days) and the underlying renal diseases glomerulonephritis/vasculitis (−69.7 days compared to diabetic nephropathy) as well as hereditary kidney disease (−117.3 days compared to diabetic kidney disease) were associated with shorter listing times. In the subset of patients who had received a living donor transplantation, compared

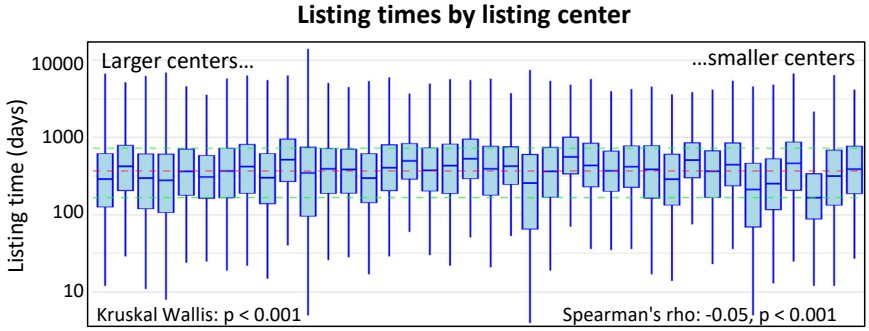


Figure 2. Listing times by listing center. Duration between dialysis and listing at 38 German transplant centers (≥250 cases per center). The median for the entire cohort is indicated by the dashed red line, with the 25th and 75th percentiles indicated by the dashed green lines. Medians of individual centers are indicated by thick dark-blue lines. The Kruskal-Wallis test was used to assess differences between center medians. Spearman's rank correlation was used to analyze the correlation between center size and listing time ($n = 43{,}394$). ETKAS, Eurotransplant Kidney Allocation System.

Table 1. Factors associated with the time from dialysis to listing on the kidney transplant waiting list

Factors			Intraclass Coefficients
Listing center			0.017
Planned living donation			0.085
Characteristic	**Estimate**	**Standard error**	***P*-value**
Intercept	602.1	±154.6	0.145
Age at dialysis (per yr)	−3.4	±0.3	<0.001
Male	9.3	±7.7	0.271
History of HIV, HBV, or HCV	278.4	±23.2	<0.001
Hemodialysis (vs. peritoneal dialysis)	164.9	±10.6	<0.001
PRA			
≤5%	-	-	-
>5–≤85%	81.5	±14.8	<0.001
>85%	234.7	±39.0	<0.001
BMI (per unit)	5.7	±0.8	<0.001
Other organ TX	−212.8	±19.9	<0.001
Blood type			
A	-	-	-
B	−0.6	±11.7	0.957
AB	55.4	±18.0	0.002
O	−16.4	±7.9	0.038
Underlying renal disease			
Diabetes mellitus	-	-	-
GN or vasculitis	−69.6	±13.0	<0.001
Hereditary	−117.3	±14.4	<0.001
Arterial hypertension	−32.5	±17.0	0.056
Postrenal	15.4	±27.4	0.574
Tubulointerstitial nephritis	0.6	±18.9	0.975
Other/unknown	2.3	±13.9	0.866

BMI, body mass index; CI, confidence interval; GN, glomerulonephritis; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; HR, hazard ratio; PRA, panel reactive antibodies; TX, transplantation.
Linear mixed model with listing time as the endpoint. Patients who had been listed preemptively were excluded from this analysis. The covariates 'listing center' and 'planned living donation' were employed as higher hierarchical levels. The amount of variance explained by these respective hierarchical levels is indicated by the intraclass coefficient, with a higher value indicating a higher amount of variance explained (maximum 1.0). Within these levels, multivariate adjustment was made for the other indicated covariates. The estimates specify the change in listing time (in days) per unit of the respective covariate. Total: 37,811 (complete case analysis; 2820 excluded because of missing data).

to diabetic nephropathy, the underlying renal diseases hereditary kidney disease (odds ratio 1.18, 95% confidence interval [CI] 1.11–1.27, $P < 0.001$), postrenal kidney disease (odds ratio 1.28, 95% CI 1.17–1.40, $P < 0.001$) and tubulointerstitial nephritis (odds ratio 1.10, 95% CI 1.00–1.19, $P = 0.032$) were associated with higher odds of receiving a preemptive kidney transplantation compared to patients with diabetic nephropathy (Supplementary Table S4).

Outcomes on the Kidney Waiting List

To evaluate the outcomes on the kidney waiting list, we focused on the patients listed who were eligible for the ETKAS program ($n = 27,662$). We investigated the primary composite endpoint of "death on the waiting list" or "permanent removal from the waiting list." Competing risk analysis adjusted for the competing event "transplantation" demonstrated that the cumulative incidence of removal or death was 15.7% ($n = 4343$) after 5 years, 28.1% ($n = 7773$) after 10 years and 31.8% ($n = 8797$) after 15 years, whereas the cumulative incidences of transplantation were 31.8% ($n = 8658$), 64.5% ($n = 17,842$) and 67.4% ($n = 18,644$), respectively (Figure 3). We identified the factors associated with poor outcomes using multivariate Fine-Gray proportional subdistribution hazards regression (Table 2). Age (per year, HR 1.03 [95% CI 1.03–1.03], $P < 0.001$), male sex (HR 1.17 [95% CI 1.10–1.24], $P < 0.001$), PRAs (per %, HR 1.01 [95% CI 1.01–1.01], $P < 0.001$), diabetic nephropathy as the underlying renal disease (HR 2.62 [95% CI 2.43–2.82, $P < 0.001$) and blood type O (HR 1.22 [95% CI 1.16–1.29], $P < 0.001$) were identified as risk factors for death on the waiting list or permanent removal. The BMI (per unit, HR 0.98 [95% CI 0.97–

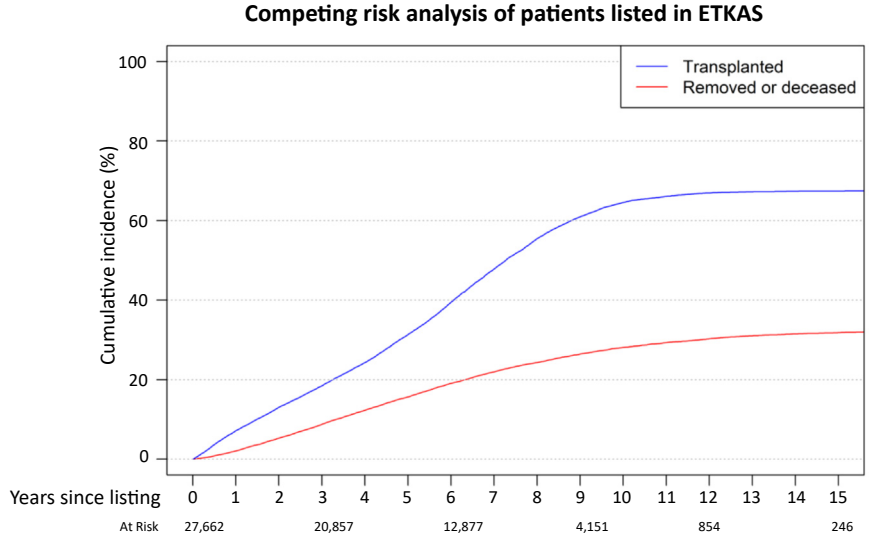


Figure 3. Outcomes on the kidney waiting list. Competing risk analysis with cumulative incidence curves for "removal from list/death on list" and the competing event "transplantation' excluding pediatric patients, candidates for old-for-old transplantation, patients with other organ transplantations and highly immunized patients ($n = 27,662$).

Table 2. Factors associated with removal from list/death on list for nonimmunized patients on dialysis aged 18 to 64 years

	Unadjusted			Adjusted		
Characteristic	HR	95% CI	*P*-value	HR	95% CI	*P*-value
Age (per yr)	1.03	1.03, 1.04	<0.001	1.03	1.03, 1.03	<0.001
Male	1.22	1.15, 1.29	<0.001	1.17	1.10, 1.24	<0.001
History of HIV, HBV, or HCV	1.05	0.90, 1.23	0.500	1.13	0.97, 1.32	0.140
Hemodialysis (versus peritoneal dialysis)	1.14	1.05, 1.25	0.003	1.04	0.95, 1.14	0.350
Listing time (per year)	1.00	0.99, 1.01	0.500	1.01	1.00, 1.02	0.210
PRA (per %)	1.01	1.01, 1.01	<0.001	1.01	1.01, 1.01	<0.001
BMI (per unit)	1.00	1.00, 1.01	0.110	0.98	0.97, 0.98	<0.001
Blood type O	1.18	1.12, 1.25	<0.001	1.22	1.16, 1.29	<0.001
Underlying renal disease: diabetic nephropathy	2.94	2.75, 3.14	<0.001	2.62	2.43, 2.82	<0.001

BMI, body mass index; CI, confidence interval; GN, glomerulonephritis; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; HR, hazard ratio; PRA, panel reactive antibodies; TX, transplantation.
Multivariate Fine-Gray proportional sub-distribution hazards regression for the primary composite end point of "removal from list or death on list" was performed using "transplantation" as the competing event. Multivariate adjustment was made for the indicated covariates. Total: 26,421, composite endpoint: 5400 (removal from list: 2498; death on list: 2902), competing endpoint: 11,791.

0.98], $P < 0.001$) was associated with a lower risk. No significant association was observed with the listing time (per year, HR 1.01 [95% CI 1.00–1.02], $P = 0.210$) a history of human immunodeficiency virus, hepatitis B, or hepatitis C infection (HR 1.13 [95% CI 0.97–1.32], $P = 0.140$) or hemodialysis instead of peritoneal dialysis (HR 1.04 [95% CI 0.95–1.14], $P = 0.350$).

DISCUSSION

Our study's findings are as follows:

1. Despite the legal obligation to promptly enroll suitable patients with end-stage renal disease in the listing process, fewer than half of the patients in deceased donor programs were listed within 1 year after initiating dialysis. Disregarding patients with potential bonus points (pediatric patients, other organ transplantations), 4.3% of patients listed within a year of dialysis onset were also transplanted within the first year. Particularly, patients in the ESP program appeared to profit from a fast listing process, partly through a higher share of rescue allocations that were accepted for these patients. This should encourage patients and nephrologists to strive for a speedy listing process.
2. The present study was the first report of national data on preemptive living donor transplantation in Germany. Although over time, the proportion of preemptive transplantations increased slightly, still less than one-third of living donor transplantations occurred preemptively. This is worrisome because there is clear evidence linking preemptive transplantation to improved outcomes.[14]
3. Listing times showed only moderate variations among transplant centers in Germany and did not correlate meaningfully with center size. The listing process was prolonged for patients with a history of viral disease, for immunized patients with high PRAs, and for patients with a higher BMI, whereas older age, peritoneal dialysis, and other organ transplantations were associated with a shorter listing process. To the best of our knowledge, our analysis is the first German analysis to assess factors associated with listing times. Several large studies have previously assessed the listing process in the United States of America, concluding that insurance status, higher BMI, low income, and ethnicity were important barriers to listing.[15,16] We confirmed the association of BMI with delayed listing in our analysis. Although data on ethnicity, income, and insurance status are not available in the German transplantation registry, these factors probably play a less dominant role in the German listing process because of the universal health care coverage in Germany.
4. The risk to be listed in ETKAS but never receive a transplant because of death or permanent removal was approximately 32%. Older patients, male patients, patients with blood type O, and patients with diabetic nephropathy as the underlying renal disease had the highest risk not to proceed to transplantation, which is in line with a previous report from theUnited States of America that found similar risk factors.[17] Confirming findings from a recent analysis from Germany,[18] higher PRA levels were associated with an increased risk for de-listing or death on the waiting list. Longer listing times were not associated with a higher risk, which was probably caused by strong collinearity of listing time with waiting time. Waiting time is the predominant factor in the ETKAS/ESP point system, and therefore, patients that are listed late have a high chance for a speedy organ allocation once they make it on the list, negating a potential disadvantage of long listing times in this group of patients.

It is important to acknowledge the limitations of our study. Our analysis was restricted to the period between 2006 and 2016, and more recent data were not available. The data source did not enable us to investigate patients with end-stage renal disease who had been evaluated for listing but did not end up on the kidney waiting list, thereby leading to selection bias. In addition, our study relied on the German transplantation registry data, which did not include certain parameters, such as detailed information on comorbidities or the number of HLA mismatches. Furthermore, the retrospective analyses precluded any causal conclusions.

Long waiting times, which are 2-fold to 3-fold higher than in the other ET member states,[1] remain the biggest hurdle for kidney transplantation in Germany; however, the slow listing process presents an additional barrier. Although this has not been adequately investigated, we presume that the implications of a slow listing process might be even greater in the other ET nations with shorter waiting times. As the first contemporary longitudinal analysis of the listing process and its outcomes within the ET area, our study indicates ample room for improvement.

DISCLOSURE

FAvS-H discloses receiving lecture fees from AstraZeneca and travel support from Chiesi GmbH (unrelated to the study). KS discloses receiving lecture fees from AstraZeneca, Novartis, Takeda Pharma and Vifor unrelated to the study). All other authors have declared no conflicting interest.

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Data Availability Statement

The data used for this study are publicly available upon request to the German transplantation registry.

AUTHOR CONTRIBUTIONS

FAvS-H performed analyses and wrote the paper. BK organized access to the data source. NK reviewed and edited the paper. HZ supervised statistical analyses. FAvS-H, BK, and KS designed the study. All authors contributed substantially to the manuscript and approved the final version.

SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

Figure S1. A flow chart of patient inclusion.

Table S1. Baseline characteristics.

Table S2. A tabular overview over patients listed within first year after dialysis onset.

Table S3. The number of listed patients by center.

Table S4. Factors associated with preemptive living donor transplantation.

STROBE Statement.

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