

RESEARCH ARTICLE

Acute diabetic foot in post kidney transplantation patients receiving chronic immunosuppression—clinical presentation and outcomes

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Abstract

Aims: Data regarding diabetic foot ulcers in patients after solid organ transplantation, particularly kidney transplantation, are limited. Chronic immunosuppression may be associated with impaired wound healing and a higher risk of amputations. In this study, we characterised the clinical presentation and outcomes of patients after kidney transplantation admitted to the diabetic foot unit, compared to non-kidney-transplant patients.

Materials and Methods: Data on the baseline characteristics, clinical presentation, and outcomes of all patients admitted to the diabetic foot unit of a large tertiary centre between the years 2014 and 2019 were collected. The most recent admission of each patient was considered. Primary outcomes were major amputations and 1 year mortality rate.

Results: During the study period, 537 patients were hospitalised, 18 of them were receiving immunosuppressive therapy due to kidney transplantation. Baseline characteristics of the patients were broadly similar, except that smoking was reported by 22.0% of the non-transplant patients and by none of the post-transplant patients ($p = 0.01$). Post-transplant patients tended to be younger (59.4 ± 11.1 vs. 65.3 ± 12.2 ; $p = 0.07$), were more likely to have type-1 diabetes (16.7% vs. 5.2%; $p = 0.07$) and had lower glucose levels upon admission (9.4 ± 4.3 vs. 12.0 ± 6.4 mmol/L; $p = 0.07$). Overall, 30% of the patients underwent major amputation, in-patient mortality rate was 9.3%, and 1 year mortality rate was 27.2%. Rates were similar in the post-transplant versus the non-post-transplant patients ($p = 0.83, 1.00, 0.59$, respectively).

Conclusions: Post-transplant patients did not incur worse outcomes in spite of immunosuppressive therapy. Limb salvage efforts should be pursued in these patients similar to the overall population.

Kobi Gorin and Avivit Cahn contributed equally to this study.

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KEYWORDS

amputation, diabetic foot ulcer, renal transplant

1 | INTRODUCTION

Lower extremity complications are common in patients with diabetes, with foot ulceration being the most frequent complication. The life-time incidence of foot ulcers is estimated between 19% and 34%, and 3.1%–11.8% of patients with diabetes have a history of foot ulceration.¹ Infection complicates over half of all diabetic foot ulcers (DFU), with many patients eventually requiring some degree of amputation.^{1,2} Patients with a DFU have 3.4 times higher risk of emergency department referral or inpatient admission compared to patients with diabetes yet without a DFU.³ The 5 year mortality rate in patients with a DFU is 2.5 times higher compared to patients with diabetes not suffering from a DFU.⁴

The most significant risk factors for the development of a DFU include peripheral neuropathy, lower extremity arterial disease (LEAD), foot deformity, and a history of a prior DFU or lower extremity amputation.⁵

Treatment of the DFU includes pressure off-loading, topical wound care, treatment of infection, surgical debridement/amputation if applicable, and vascular reinstatement if necessary.⁶ Addressing the patient's overall medical status is of vital importance with careful consideration of glycaemic control, nutritional status, control of oedema, and awareness of possible exacerbation of chronic comorbidities. Approximately 23% of the ulcers fail to heal within 1 year.⁷ Impaired wound healing is associated with LEAD, peripheral neuropathy, end-stage renal disease, heart failure, inability to walk or stand independently, and larger ulcer size.⁷ Poor glycaemic control—hyperglycemia, hypoglycemia, or lower time in range are all associated with amputations and poor outcomes in patients hospitalised with acute diabetic foot.^{8,9}

The incidence of DFU is greater in patients with diabetes and concurrent chronic kidney disease, with generally worse outcomes including higher amputation rates and poor survival.^{10–13} Patients with diabetes requiring renal replacement therapy, compared to diabetic patients with CKD stage 4–5 (eGFR <30 ml/min/m²), demonstrated a higher prevalence of prior amputations, prior foot ulceration, and prevalent foot ulceration.¹⁴ Wolf et al. demonstrated a negative correlation between DFU and estimated glomerular filtration rate (eGFR); for every 10 ml/min increase in eGFR the odds for developing DFU decreased by 30% in patients with type 1 diabetes, and by 13% in patients with type 2 diabetes.¹⁵

The use of immunosuppressive therapy in patients after solid organ transplantation places patients at an increased risk of impaired wound healing.¹⁶ In a recent study, Vrátná et al.¹⁷ followed 57 diabetic patients after organ transplantation, of whom 50 patients underwent simultaneous pancreas-kidney (SPK) transplantation, and 7 patients underwent pancreas transplantation alone. During the follow-up period, about a third (31.6%) developed a diabetic foot

ulcer. The predominant risk factors were the presence of LEAD, foot deformities, and leisure-time physical activity (LTPA) before transplantation. Sharma et al. showed that the occurrence of a DFU in kidney transplant patients also predicted a fivefold increase in the risk of transplant failure. Interestingly, DFU development had no impact on transplant failure in SPK transplantation patients.¹⁸ A small study which compared 9 DFU post-transplant patients (7 kidney, 1 liver, 1 pancreas) to 14 patients with diabetes and no history of solid organ transplantation, noted a significant difference in healing times—111 ± 25 days in the post-transplantation group versus 47 ± 18 in the controls.¹⁹

In contrast, routine follow-up of patients post kidney transplantation suffering from a DFU in a multidisciplinary foot clinic showed lower major amputation rates compared to previous years, and healing times of the DFUs were similar to those previously reported in non-transplanted patients with diabetes.²⁰

In this study, we aim to characterise the clinical presentation and outcomes of patients receiving immunosuppressive therapy due to kidney transplantation, compared to non-kidney-transplant patients hospitalised in our diabetic foot unit during that time.

2 | PATIENTS AND METHODS

2.1 | Study design

This is a retrospective study performed at a single tertiary university teaching hospital. We evaluated the electronic medical records of all patients admitted to the Diabetic Foot Unit in Hadassah Hebrew University Hospital between the years 2014 and 2019. This study was approved by the hospital's ethical committee.

2.2 | Study population

All patients hospitalised in the diabetic foot unit for at least 1 day during the years 2014–2019 due to an acute diabetic foot were included in the study. Acute diabetic foot was defined as a DFU with acute infection or acute/critical limb ischaemia. Additional inclusion criteria were age over 18 years and a known diagnosis of diabetes mellitus (type 1 or 2).

2.3 | Data collection

Clinical, demographic, and laboratory data were collected from the electronic medical records. Laboratory data collected were those documented upon admission. The eGFR was calculated using the

CKD-EPI formula. The clinical presentation of the DFU is based upon the text describing the DFU and supporting imaging. The Wagner, SINBAD, and IDSA scores were assigned to the patients by 2 independent authors (ML and SP), and disagreements were resolved by discussion with AC. The patient was considered to have osteomyelitis based on a positive culture from a bone specimen, documented positive probe to bone test or visible bone, or by evidence of osteomyelitis on imaging studies. Neuropathy was confirmed based on the physical examination documented by the physician or nursing staff upon admission. Patients with classical plantar wounds were also considered to have neuropathy. Length of hospitalisation was considered from the day of admission to the hospital till the discharge date, irrespective of the department, providing that the patient was hospitalised in the Diabetic Foot Unit for at least 1 day.

2.4 | Outcomes

The primary outcomes were (1): major amputation during hospitalisation, defined as amputation proximal to the calcaneus bone; (2) mortality rate during the first year after discharge. Secondary outcomes included: (1) any amputation during hospitalisation and (2) length of hospitalisation.

2.5 | Statistical analysis

Data presented are mean \pm SD or median (IQR) for continuous variables and N (%) for categorical variables. We compared patients following transplantation versus not using the Chi-test or Fischer's

test for categorical variables and the Mann-Whitney test for continuous variables.

The statistical analyses for this study were generated using IBM SPSS statistics, version 25.

3 | RESULTS

Overall, 537 patients were included in this study, including 18 post kidney transplantation (Figure 1). The baseline characteristics of the patients are shown in Table 1. There were no significant differences between the groups, apart from smoking (Table 1). There was a notable trend for lower age (59.4 ± 11.1 vs. 65.3 ± 12.2) and a higher proportion of type 1 diabetes in the post-transplant patients. The groups did not differ in their clinical presentation with a similar mean total SINBAD score (4.5 ± 1.04 vs. 4.57 ± 1.14 ; $p = 0.63$) in the post transplantation and control groups, respectively. Wagner score was also similar across the groups.

Overall, 56.8% of all patients underwent any amputation during their hospitalisation. Fifty patients (9.3%) died during hospitalisation, and the 1 year mortality rate was 27.2% (Table 2). Amputation rates were similar between the groups (Figure 2; Table 2), with 27.8% of patients requiring major amputation in the post-transplantation group and 30.1% in the controls ($p = 0.83$). One-year mortality rate in the post-transplantation and controls was 33.3% and 27%, respectively ($p = 0.59$). There was no significant difference regarding length of hospitalisation and in-hospital mortality ($p = 0.15$ and $p = 1$, respectively; Table 2).

Table 3 provides patient-level data of the post transplantation group. Type 1 diabetes was noted in 3 patients who had undergone simultaneous kidney and pancreas transplantation. Additionally, graft

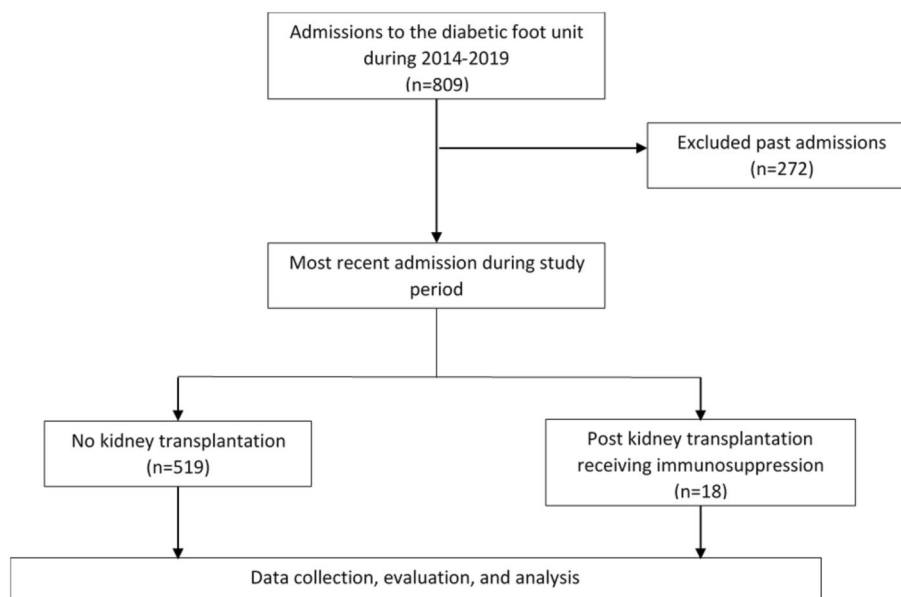


FIGURE 1 Consort diagram

TABLE 1 Baseline characteristics of the patients upon admission by transplantation status

	Overall N = 537	Post kidney transplantation N = 18	No kidney transplant N = 519	p value
Male sex, N (%)	402 (74.9%)	14 (77.8%)	388 (74.8%)	1.00
Age, y, mean \pm SD	65.1 \pm 12.2	59.4 \pm 11.1	65.3 \pm 12.2	0.07
Type 2 diabetes	507 (94.4%)	15 (83.3%)	492 (94.8%)	0.07
Insulin use	347 (64.4%)	10 (55.6%)	337 (64.9%)	0.41
Current smoking	114 (21.2%)	0 (0%)	114 (22.0%)	0.01
IHD	253 (47.1%)	5 (27.8%)	248 (47.8%)	0.09
PVD	384 (71.5%)	15 (83.3%)	369 (71.1%)	0.25
Previous amputation	219 (40.8%)	7 (38.9%)	212 (40.8%)	0.86
Prior hospitalisation (6 months)	338 (62.9%)	12 (66.7%)	326 (62.8%)	0.73
Recent antibiotic therapy (3 months)	335 (62.4%)	13 (72.2%)	322 (96.6%)	0.38
Kidney function at baseline (mL/min/1.73 m ²)				
eGFR >60	251 (40.0%)	8 (44.4%)	207 (39.9%)	0.61
eGFR 30–60	144 (26.8%)	5 (27.8%)	139 (26.8%)	
eGFR <30	68 (12.7%)	2 (11.1%)	66 (12.7%)	
Dialysis	110 (20.5%)	3 (16.7%)	107 (20.6%)	
Temp, c	36.8 \pm 0.5	36.8 \pm 0.3	36.8 \pm 0.5	0.92
Glucose, mmol/L	11.9 \pm 6.3	9.4 \pm 4.2	12.03 \pm 6.4	0.07
WBC, 10 ³ / μ l	13.2 \pm 5.9	11.4 \pm 3.5	13.2 \pm 6.0	0.27
CRP, mg/dl	13.96 \pm 10.60	9.62 \pm 6.60	14.11 \pm 10.68	0.11
Known osteomyelitis	232 (43.2%)	5 (27.8%)	227 (43.7%)	0.17
Midfoot/hindfoot ulcer	248 (46.2%)	8 (44.4%)	240 (46.6%)	0.86
Neuropathy	313 (58.3%)	8 (44.4%)	305 (59%)	0.21
SINBAD total, mean \pm SD		4.5 \pm 1.04	4.57 \pm 1.14	0.63
Wagner score 1–2	72 (13.5%)	2 (11.1%)	70 (13.5%)	0.35
Wagner score 3	179 (33.5%)	4 (22.2%)	175 (33.8%)	
Wagner score 4–5	284 (53.1%)	12 (66.7%)	272 (52.6%)	

Abbreviations: CRP, c-reactive protein; eGFR, estimated glomerular filtration rate; IHD, ischaemic heart disease; PVD, peripheral vascular disease; WBC, white blood cells.

TABLE 2 Primary and secondary outcomes overall and by transplantation status

	Overall N = 537	Post kidney transplantation N = 18	No kidney transplantation N = 519	p value
Any amputation	305 (56.8%)	10 (55.6%)	295 (56.8%)	0.91
Major amputation	161 (30%)	5 (27.8%)	156 (30.1%)	0.83
Inpatient mortality	50 (9.3%)	1 (5.6%)	49 (9.4%)	1.00
1 year mortality	146 (27.2%)	6 (33.3%)	140 (27%)	0.59
Duration of stay, days, median (IQR)	17 (9–29)	24 (15.75–34.25)	17 (9–29)	0.15

failure was noted in 3 patients who were undergoing dialysis treatment. Of note, these patients continued to receive immunosuppressive therapy, as is the common practice, to prevent rejection of

potentially subsequent transplants and were therefore included in the appropriate cohort. The median time from transplantation to admission was 5.74 \pm 5.13 years. Immunosuppressive regimen varied

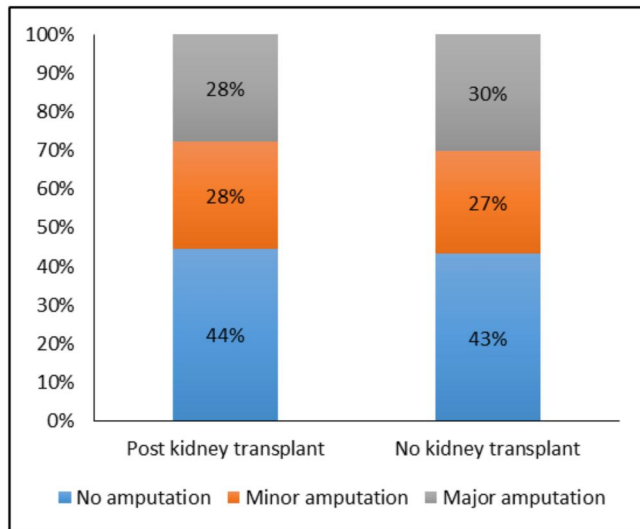


FIGURE 2 Patient outcomes by transplantation status

among patients, 88% received prednisone, 83% received tacrolimus, and 72% received mycophenolate mofetil. Ten patients underwent some level of amputation.

4 | DISCUSSION

In this study, we describe the baseline characteristics, clinical presentation, and outcomes of post-kidney transplant patients admitted to the diabetic foot unit, compared to non-transplant patients admitted to the unit during the same period. The clinical presentation of our patients was severe (Wagner score 4–5, Sinbad score >4), yet did not differ between the groups. Over half of the patients underwent any amputation, with 27.8% requiring major amputation. No significant differences in outcomes were noted between post-kidney transplantation patients and controls.

Previous studies noted worse outcomes in post-transplant patients presenting with a DFU compared to non-transplant patients. In a cohort of 27 patients with diabetes post kidney transplantation, 6 (22%) underwent amputation, as compared to 1 patient (1.8%) in the control group.²¹ In a more recent study, Woeste et al. examined 200 patients after a combined kidney-pancreas transplantation, 19 (9.5%) patients underwent an amputation. A history of prior amputation and the duration of dialysis treatment prior to transplantation were associated with an increased risk of amputation.²² Misra et al. examined 118 DFU patients, 12 of whom (10.8%) underwent post-kidney transplant. Median time to development of DFU after kidney transplantation was 26.5 months, gangrene was present in 25%, and 41.6% had systemic signs of infection.²³ Of the post-transplantation cohort, half required toe amputation, 16.6% required forefoot amputation, and 25% required below knee amputation. One patient (8.3%) died during the

hospitalisation due to septicaemia, rates broadly similar to our cohort. Fejfarova et al. compared microbial findings in 207 DFU patients, comparing post-transplant patients and haemodialysis patients to all other patients. Study groups did not differ in ulcer severity or types of microorganisms; however, there was a significant difference in occurrence of microbial resistance to antibiotics. Post-transplant patients were more likely to have resistant microorganisms, specifically *staphylococcus aureus* and *enterococcus* species.²⁴

We anticipated worse outcomes in the post-transplant group, due to immunosuppressive therapy. Yet, in this study there were no significant difference in outcomes. One possible explanation is close monitoring and more frequent clinic visits of the post-transplant patients. Furthermore, these patients undergo a thorough evaluation before deemed eligible for transplantation, with optimization of therapy for other comorbidities. They may also be more motivated for self-care (as can be seen by the lower rate of smokers in the transplantation group).

Several limitations of our study should be noted. This is a retrospective study design, thus the description of DFU extent and severity is based upon interpretation of the subjective appreciation of the attending physician. Nonetheless, this study was conducted in a single medical centre, on a well specified clinical cohort. We can assume with high probability that evaluation and management (surgical and medical) were similar among patients in our study cohort.

We conclude that data regarding diabetic foot disease in patients after kidney transplantation is limited. Still, in our trial, post-transplant patients did not incur worse outcomes in spite of immunosuppressive therapy. Limb salvage efforts should be pursued in these patients similar to the overall population.

CONFLICTS OF INTEREST

The authors have no conflicts of interest pertaining to this publication to report.

DATA AVAILABILITY STATEMENT

The datasets analysed during the current study are not publicly available due to patient privacy but are available from the corresponding author on reasonable request.

ETHICS STATEMENT

The study was approved by the local Helsinki Committee of the hospital.

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PEER REVIEW

The peer review history for this article is available at <https://publons.com/publon/10.1002/dmrr.3575>.

TABLE 3 Baseline characteristics and outcomes of post kidney transplantation patients

Age (years) gender	Type of DM	Type of tx	Time from tx to admission (years)	Immunosuppressive therapy (daily dosage)	GFR on admission (ml/min /m ²)	Previous amputation	Wagner SINBAD	Duration of stay (days)	Amputation	Inpatient mortality	1 year mortality
1 75M	2	Kidney	9.03	Prednisone 5 mg, tacrolimus 2 mg, MMF 1000 mg	95.49	-	3	4	-	-	-
2 65M	2	Kidney	6.86	Prednisone 5 mg, tacrolimus 1 mg	80.18	+	4	4	23	-	-
3 57M	2	Kidney	14.41	Prednisone 5 mg	Dialysis	-	4	4	70	BKA	+
4 60M	2	Kidney	0.35	Prednisone 5 mg, tacrolimus 4 mg, MMF 720 mg	40.99	-	4	5	35	Toe	+
5 38F	1	Kidney + pancreas	1.16	Prednisone 5 mg, tacrolimus 4 mg, MMF 360 mg	35.12	+	1	4	21	BKA	-
6 71M	2	Kidney	10.98	Prednisone 5 mg, tacrolimus 2 mg, MMF 750 mg	20.27	-	4	4	16	-	+
7 64M	2	Kidney	0.45	Tacrolimus 1 mg, MMF 1000 mg	63.59	-	4	6	25	-	-
8 65M	2	Kidney	5.24	Prednisone 15 mg, tacrolimus 8 mg, MMF 500 mg	39.27	+	4	4	34	-	+
9 65F	2	Kidney	4.96	Prednisone 5 mg, tacrolimus 6.5 mg, MMF 500 mg	38.86	+	4	6	42	First ray	+
10 60M	2	Kidney	7.38	Prednisone 10 mg, azathioprine 50 mg	13.17	-	4	6	48	AKA	-
11 69F	2	Kidney	3.03	Prednisone 5 mg, tacrolimus 3 mg	Dialysis	-	4	5	29	TMA	+
12 64M	2	Kidney	19.76	Prednisone 5 mg, cyclosporine 125 mg	Dialysis	-	4	5	18	BKA	+
13 64M	2	Kidney	4.46	Prednisone 5 mg, tacrolimus 1 mg, MMF 1000 mg	70.79	-	5	6	12	BKA	+
14 64M	2	Kidney	5.85	Prednisone 5 mg, tacrolimus 7 mg, MMF 1080 mg	81.88	-	1	3	4	-	+
15 50M	2	Kidney	2.88	Tacrolimus 3.5 mg, MMF 500 mg	92.95	+	3	4	15	-	-
16 62M	2	Kidney	1.98	Prednisone 5 mg, tacrolimus 3 mg, MMF 180 mg	48.14	-	3	3	18	-	-
17 41M	1	Kidney + pancreas	1.88	Prednisone 5 mg, tacrolimus 6 mg, MMF 360 mg	100.46	+	3	3	25	Toe	-
18 36F	1	Kidney + pancreas	2.72	Prednisone 5 mg, tacrolimus 3 mg, MMF 360 mg	63.17	+	4	4	26	Sesamoids	-

Abbreviations: AKA, Above knee amputation; BKA, Below knee amputation; F, Female; GFR, estimated glomerular filtration rate; M, Male; MMF, Mycophenolate mofetil; TMA, transmetatarsal amputation; tx, transplantation.

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