

2022-04

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<http://hdl.handle.net/10026.1/19147>

10.6002/ect.2021.0500

Experimental and Clinical Transplantation

Baskent University

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Implantable Doppler Probe as a Vascular Monitoring Device in Kidney Transplant Patients: Investigation of Use at a Single Center

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Abstract

Objectives: Vascular complications account for 30% to 35% of total kidney grafts lost during the first 3 months posttransplant. Early detection of vascular complications allows an opportunity for prompt intervention, which is critical to reducing graft loss. In this study, we evaluated the usefulness of an implantable Doppler probe as a vascular monitoring device in kidney transplant patients.

Materials and Methods: An implantable Doppler probe is used intermittently for postoperative monitoring of kidney transplant patients at our center. In this retrospective study, we analyzed prospectively maintained medical data in which we compared clinical outcomes of kidney transplant recipients who had postoperative implantable Doppler probe monitoring versus standard care clinical observation. Between January 2016 and October 2021, 324 kidney transplant patients were seen at our center. Patients were divided into 2 groups: group 1 (n = 194; 60%) included kidney transplant recipients with postoperative implantable Doppler probe monitoring and group 2 (n = 129; 40%) included kidney transplant recipients with standard care clinical observation. We compared number of vascular complications, number of departmental ultrasonographic scans required posttransplant, and graft loss at 3 months between the 2 groups.

Results: Vascular complications were identified in 13.5% of total patients, with graft loss identified in 2.1%. Both groups were similar in demographical characteristics. Group 1 had more vascular complications (17.5% vs 9.3%; relative risk = 1.88), fewer

ultrasonographic scans during the first 24 hours posttransplant (71.1% vs 83.7%; relative risk = 0.84), and lower graft loss (1.5% vs 3.1%; relative risk = 0.48) than group 2. All probes were removed safely after 72 hours, and no complications related to the device were reported.

Conclusions: The monitoring device may be used as an additional adjunct for graft monitoring in kidney transplant patients. Further controlled studies are warranted to evaluate this device in clinical practice.

Key words: Blood flow, Graft perfusion surveillance, Renal transplantation

Introduction

Around 3 million people in the United Kingdom have chronic kidney disease.¹ The UK annual mortality associated with kidney failure is 100 000 deaths per year; this corresponds to 10 people every hour.¹ In Europe, 50% of patients with end-stage renal disease (ESRD) die within 5 years as a result of complications.²

The high mortality associated with ESRD can be significantly reduced by kidney transplantation.^{3,4} However, the increased incidence of ESRD has further widened the disparity between the number of transplant kidneys available for donation and their high demand.⁵ There are presently 6000 patients on the UK transplant waiting list with about 10 patients added daily.⁶ The average UK kidney transplant wait time is about 30 months.⁷ Every day, a patient with ESRD will die waiting for a transplant, and only 1 in 4 will be able to receive a suitable kidney transplant.¹ The prevailing uncertainty and the unprecedented reduction of transplant activity due to the COVID-19 pandemic have further increased the shortage of organs.⁸

Adding to the problem, about 7% to 8% of the grafts are lost in the first 3 months after transplant.⁹ One-third of this loss is due to vascular

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Acknowledgements: The authors have not received any funding or grants in support of the presented research or for the preparation of this work and have no declarations of potential conflicts of interest.

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complications.¹⁰ To counter graft disparity, it is paramount to ensure the survival of the transplanted organs.¹¹ Early detection of vascular complications allows an opportunity for a prompt intervention that is vital to reducing graft loss. A delay in the diagnosis will result in thrombosis of the graft after which it is unsalvageable.¹² The early diagnosis can be challenging due to the absence of consistent parameters that can be used to assess graft function. Patients with compromised graft perfusion are clinically asymptomatic in the initial phase. Similarly, other indicators of graft function, like a drop in serum creatinine¹³ and production of urine,¹⁴ are unreliable.

Traditionally, Doppler ultrasonographic scans are used as an imaging study to assess the perfusion of the transplanted kidneys postoperatively.¹² The Doppler ultrasonographic scan is noninvasive, portable, and has 97% sensitivity of detecting graft hypoperfusion.¹⁵ Despite that, the scan has operative and administrative limitations, and cases can still be missed.¹⁰ Similarly, it provides information on graft perfusion only during the scanning process.¹⁶ As a result, serial ultrasonographic scans are required in challenging cases.¹⁷

The implantable Doppler probe is a vascular monitoring device with the ability to provide continuous, easily interpretable, and reliable audible Doppler signals that can be used to monitor blood flow to the graft.¹² It is used postoperatively to monitor the patency of vascular anastomosis and graft perfusion in cardiovascular, liver transplant, plastic, and breast reconstructive surgeries.¹⁸⁻²¹

On the same principle, this device may have a possible role in the early identification of vascular complications critical to reducing graft loss.²² In this study, we aimed to evaluate the usefulness of the implantable Doppler probe as a vascular monitoring device in kidney transplant patients.

Materials and Methods

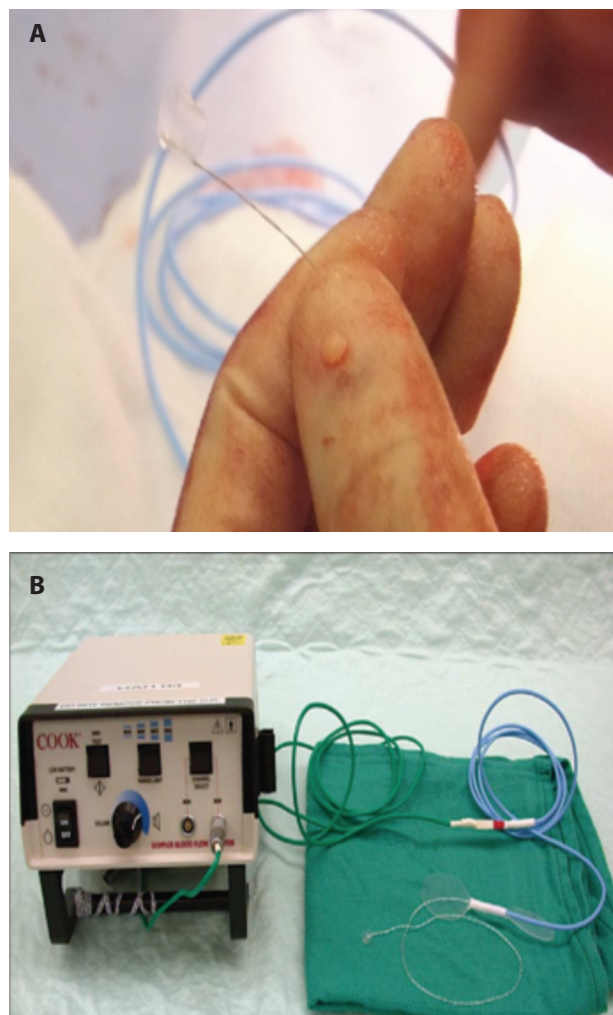
The implantable Doppler probe has been used intermittently for the postoperative monitoring of kidney transplant patients at our center for the past 9 years. Data of all kidney transplant recipients between January 2016 and October 2021 were extracted retrospectively from the prospectively maintained patient database at the Southwest Transplant Centre (Plymouth, UK). Patients who had

a kidney transplant with postoperative implantable Doppler probe monitoring were considered as group 1, and kidney transplant patients who received standard care clinical observation were considered as group 2. Surgical outcomes between groups were compared.

Ethical approval (reference No. CA_2019_20_209) was obtained from the Research and Development Department of the University Hospitals Plymouth NHS Trust where data compilation and analysis were conducted.

The implantable Doppler probe (Cook-Swartz) consists of a 20-MHz crystal transducer that is attached to a silicone cuff.²³ During kidney transplant surgery, the probe is attached to the renal artery (Figure 1). The scientific basis of the probe is provided by the transducer that converts the kinetic

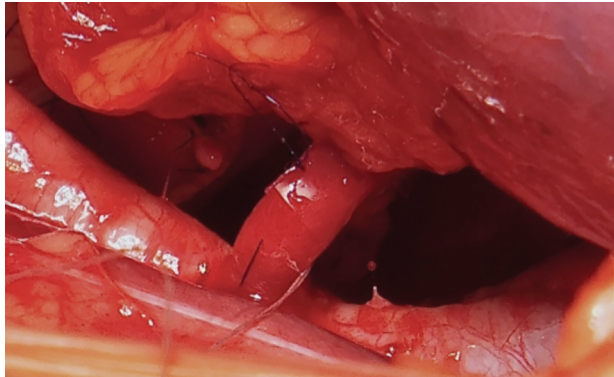
Figure 1. Implantable Doppler Flow Probe



(A) Cook-Swartz Implantable Doppler flow probe showing silicon cuff and flexible wire in the background. (B) Cook-Swartz Implantable Doppler flow probe, with connecting wire and external monitoring device.

energy of the pulsatile blood flow in the vessel into electric energy. A wire connects the probe to the external monitor that translates this energy into audible Doppler signals (Figure 2). The continuous signals represent forward systolic shifts and are used to monitor blood flow to the graft. Impairment of blood flow to the graft results in the cessation of audible signals and is interpreted as graft hypoperfusion. Cessation of audible signals allows an early warning sign warranting immediate assessment if the patient is still in the operating theatre or further investigations if in the transplant ward. Kidney transplant recipients at our center who receive a postoperative implantable Doppler probe are monitored continuously for the first 4 hours from the graft perfusion in the operating theatre and recovery. After patients are shifted to the transplant ward, they are monitored intermittently in the next 72 hours depending on their graft function. The wire connecting the probe to the monitor is disengaged by gentle traction after 72 hours; however, the cuff is left around the vessel.

Figure 2. Cook-Swartz Implantable Doppler Flow Probe In Situ Around the Renal Artery



All deceased or living donor kidney transplant recipients who had the implantable Doppler probe monitoring or who had standard care clinical observation at our center during the study period were included in the study. However, patients who received a graft with 2 or more donor renal arteries evident at the time of surgery were excluded. The eligibility criteria were applied to maintain standardization of the data collection by selecting data only from single vessel transplant kidneys. In addition, multiple renal artery grafts, compared with single renal artery grafts, are associated with a higher risk of posttransplant complications.²⁴

Data of all eligible patients were collected retrospectively through Vital Data. The Vital Data database is a prospectively maintained and audited database system used in the NHS for management of patients with chronic kidney disease.²⁵ Individual medical notes of patients were consulted for further clearance. The data collected included demographic characteristics and surgical outcomes after kidney transplant surgery (Table 1).

The extracted data were anonymized, transcribed, and processed in a Microsoft Excel worksheet. Demographic characteristics of kidney transplant recipients in both groups were summarized using descriptive statistics such as means and standard deviations. Posttransplant surgical outcomes are expressed in percentages.

Demographic characteristics were compared between groups to assess whether they were identical. Similarly, surgical outcomes in both groups were compared to assess whether there were any substantial changes in surgical outcomes in kidney transplant recipients who had postoperative implantable Doppler probe monitoring versus standard care clinical observation.

We also calculated relative risk (RR) to describe the strength of the relationship between the surgical outcomes and the application of implantable Doppler probe monitoring.

The RR for each surgical outcome was calculated by the following formula: (% in group of kidney transplant recipients with the implantable Doppler

Table 1. Collected Demographic Characteristics and Surgical Outcomes After Kidney Transplant Surgery in Study Participants

<i>Demographic Characteristic</i>
a) Age at the time of operation, sex, and BMI
b) Dialysis modality at the time of transplant
c) Time on the kidney transplant wait list
d) Source of the donated kidney (living vs deceased donor)
e) Prior renal transplant
f) Surgeon undertaking the procedure (coded to maintain anonymity)
g) Recipient risk factors for transplant surgery (age >70 y, BMI >30, cardiovascular disease, smoking, peripheral vascular disease, thromboembolic disease, hypertension, diabetes mellitus, and urological obstructive symptoms)
h) Donor risk factors for transplant surgery (donor age >60 y, cold ischemia time, number of renal arteries on graft, smoking, cardiovascular disease, hypertension, diabetes mellitus, and any cerebrovascular events)
<i>Surgical Outcome After Kidney Transplant</i>
a) Number of vascular complications identified
b) Number of departmental ultrasonographic scans requested in the first 24, 48, and 72 hours posttransplant
c) Number of grafts lost because of vascular complications in the first 3 months

Abbreviations: BMI, body mass index (in kilograms divided by height in meters squared)

probe monitoring)/(% in group of kidney transplant recipients with standard care clinical observation).

Results

Data on 324 kidney transplant recipients were included in the study. Of the 324 total participants, 214 (66%) were men and 110 (34%) were women. The mean age of the participants was 53 ± 15.23 years. The mean body mass index (in kilograms divided by height in meters squared) of participants was 27.27 ± 4.98 . The average wait time for a patient to have a matched kidney transplant (from being activated on the national transplant waiting list to kidney transplant surgery) was 637 days. There were 194 patients in group 1 (60% of total sample size) and 129 patients in group 2 (40% of total sample size).

Comparison of demographic characteristics between the groups

Demographic characteristics were similar between the 2 groups, allowing a direct comparison of surgical outcomes between the groups. Table 2 provides details of demographic characteristics for each group. Table 3 summarizes the results of this study.

Comparison of early vascular complications identified in both groups

Among the total participants (N = 324), there were a total of 46 early vascular complications identified in the previous 5 years, which is 14.1% of the total. We defined early vascular complications as clinically or radiologically diagnosed hypoperfusion of the graft due to thrombosis, kinking, or torsion of the renal artery or renal vein. The causes of early vascular complications that we encountered were positional hypoperfusion, anastomotic narrowing, intimal flap, and arterial dissection.

When we reviewed early vascular complications in the respective groups, there were 34 complications (17.5%) among 194 participants in group 1 and 12 complications (9.30%) among 129 participants in group 2. The relative risk was $17.5/9.30 = 1.88$.

Comparison of the number of departmental ultrasonographic scans requested postoperatively in both groups

Among the 194 participants in group 1, there were 138 (71.1%) departmental ultrasonographic scans required in the first 24 hours versus 108 scans (83.7%) required among the 129 participants in group 2. Thus, there was a 12.6% reduction in group 1. The relative risk was 0.84. Over the next 48 and 72 hours, there was only a slight difference in the number of departmental scans requested for both groups.

Table 2. Demographical Characteristics in Group 1 Versus Group 2

Characteristic	Kidney Transplant Recipients (N = 324) Group 1: With Implantable Doppler Flow Probe Monitoring (n = 194)	Group 2: With Standard Care Clinical Observation (n = 129)
Recipient mean age \pm SD, y	52 ± 16.11	51 ± 17.20
Recipient BMI	26.52	27.56
Sex, %		
Male	67%	61%
Female	33%	39%
Mode of dialysis, %		
HD	51%	57%
PD	17%	19%
Commonest CKD etiology	APKD, DM, IgA nephropathy	APKD, DM, IgA nephropathy
Donor mean age \pm SD, y	51 ± 15.23	53 ± 16.66
Type of donor kidney, %		
DCD	31%	34%
DBD	35%	39%
LKD	34%	27%

Abbreviations: APKD, autosomal polycystic kidney disease; BMI, body mass index (in kilograms divided by height in meters squared); CKD, chronic kidney disease; DBD, deceased brain dead; DCD, deceased circulatory dead; DM, diabetes mellitus; HD, hemodialysis; IgA, immunoglobulin A; LKD, living kidney donor (all were >18 years and relatives [up to fourth degree] or spouse of recipients); PD, peritoneal dialysis

Table 3. Summary of the Results

Surgical Outcome	Group 1: With Implantable Doppler Flow Probe Monitoring (n = 194)	Group 2: With Standard Care Clinical Observation (n = 129)	Total Kidney Transplant Participants (N = 324)
Early vascular complication (RR = 1.88)	34/194 (17.5%)	12/129 (9.3%)	46/324 (13.5%)
Departmental ultrasonographic scans requested in first 24 h posttransplant (RR = 0.84)	138/194 (71.1%)	108/129 (83.7%)	12.6% reduction
Graft loss because of vascular complications in first 3 mo (RR = 0.4)	3/194 (1.5%)	4/129 (3.1%)	7/324 (2.1%)

Abbreviations: RR = relative risk

Group 1 had more vascular complications, fewer departmental ultrasonographic scans requested in the first 24 h posttransplant, and fewer incidences of graft loss and delayed graft function in the transplanted kidneys because of vascular complications compared with group 2.

Comparison of number of grafts lost as a result of vascular complications in the first 3 months in both groups

The number of grafts lost due to vascular complications in group 1 ($n = 194$) was 3 (1.5%), whereas there were 4 grafts lost (3.1%) in group 2 ($n = 129$). The relative risk was $1.5/3.1 = 0.4$.

Discussion

The rate of vascular complications after renal transplant can range from 3% to 15%.²⁶ This variance was due to different inclusion criteria, depending on the definition of vascular complications adopted by different groups. Some groups have only considered early vascular complications, whereas others have accounted for early and delayed vascular complications together.²⁷ Despite the differences, a consensus remains that the high morbidity and graft loss associated with vascular complications can be reduced with early diagnosis and prompt management.²⁸

Our study investigated the usefulness of an implantable Doppler probe in kidney transplant patients, with the aim to assess its role as a vascular monitoring device and in the identification of vascular complications in the postoperative kidney transplant setting. To assess the benefits of an intervention, it is paramount to select appropriate outcome measures that can be compared between groups. There are multiple risk factors for delayed graft function in kidney transplant recipients.²⁹ Therefore, it was not considered as a surgical outcome to prevent the introduction of confounding factors in the study.

The results revealed that in group 1 more early vascular complications were reported and fewer departmental ultrasonographic scans were requested in the first 24 hours posttransplant compared with results shown in group 2. Application of the implantable Doppler probe may have played a possible role in the identification of a higher number of vascular complications. Similarly, the continuous monitoring allowed by the probe may have led to the satisfaction of clinicians who requested fewer departmental ultrasonographic scans. A recent study conducted in London involving the use of the probe in 15 consecutive living donor kidney transplant recipients reported implantable Doppler probe as a successful additional method of monitoring blood

flow to the graft.³⁰ A reliable vascular monitoring device could reduce the financial costs to health care systems and allow radiology resources to be diverted to other emergencies.

Graft loss as a result of vascular complications was lower in group 1 than in group 2. This may be attributed to the ability of the implantable Doppler probe to detect vascular complications at an early stage. A timely surgical correction is crucial to improve the outcome of a compromised graft. In line with our findings, a case report from London mentioned a successful early detection of a vascular complication in a kidney transplant from a living donor. An implantable Doppler probe allowed a timely diagnosis of graft hypoperfusion that was salvaged by critical repositioning.¹²

We did not experience any immediate complications related to the monitoring device, and all probes were removed easily. This is concordant with the findings of an earlier study.²⁹ However, a recent case report from Canada described a free flap anastomotic leakage from the traction applied to disengage the probe.³¹ Such an incident would be catastrophic in kidney transplant recipients. Late complications with the use of the probe, namely vessel constriction at the probe application site, can increase tension on the anastomosis, and false-negative detection rates require evaluation by further prospective studies.

The monitoring device only offers an indirect assessment of the venous return as the probe is attached to the renal artery. The renal vein, particularly on the right side, is thin walled and carries a risk of avulsion during disengagement of the probe.

Our study is the largest reported series of kidney transplant patients with application of an implantable Doppler probe. Although the results were suggestive of the utility of the monitoring device, this study had limitations. Over the 5-year data collection period, there were chances of discrepancy in the recorded data shown in the patient notes. There was also an inherent selection bias in this study as all the cases in each group were operated by the same pair of surgeons. Only half of the transplant surgeons in our center used the monitoring device, and surgeon crossover critical for the study was absent. Similarly, 72% (68/95) of the total living kidney donor transplant recipients in our study were in group 1. A kidney transplant from a living donor as opposed to a deceased donor is of

high quality and can have fewer complications.³² The effects of the surgeon's expertise and the type of kidney donor on the differences shown in surgical outcomes between the 2 groups cannot be ruled out.

The primary purpose of this study was to inform the local practice and generate preliminary information for future clinical studies. Because this study was undertaken in kidney transplant patients in the NHS hospital settings, the findings carry the potential to be assessed further in other units.

Conclusions

An implantable Doppler probe allows continuous blood flow monitoring of the transplanted kidney. This device may be used as an additional adjunct to the departmental ultrasonographic scan for graft monitoring in kidney transplant recipients. Further controlled studies are warranted to evaluate this device in clinical practice.

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