

Impact of Navigators on First Visit to a Transplant Center, Waitlisting, and Kidney Transplantation

A Randomized, Controlled Trial

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Abstract

Background and objectives Many patients with ESKD face barriers in completing the steps required to obtain a transplant. These eight sequential steps are medical suitability, interest in transplant, referral to a transplant center, first visit to center, transplant workup, successful candidate, waiting list or identify living donor, and receive transplant. This study sought to determine the effect of navigators on helping patients complete these steps.

Design, setting, participants, & measurements Our study was a cluster randomized, controlled trial involving 40 hemodialysis facilities and four transplant centers in Ohio, Kentucky, and Indiana from January 1, 2014 to December 31, 2016. Four trained kidney transplant recipients met regularly with patients on hemodialysis at 20 intervention facilities, determined their step in the transplant process, and provided tailored information and assistance in completing that step and subsequent steps. Patients at 20 control facilities continued to receive usual care. Primary study outcomes were waiting list placement and receipt of a deceased or living donor transplant. An exploratory outcome was first visit to a transplant center.

Results Before the trial, intervention (1041 patients) and control (836 patients) groups were similar in the proportions of patients who made a first visit to a transplant center, were placed on a waiting list, and received a deceased or living donor transplant. At the end of the trial, intervention and control groups were also similar in first visit (16.1% versus 13.8%; difference, 2.3%; 95% confidence interval, -0.8% to 5.5%), waitlisting (16.3% versus 13.8%; difference, 2.5%; 95% confidence interval, -1.2% to 6.1%), deceased donor transplantation (2.8% versus 2.2%; difference, 0.6%; 95% confidence interval, -0.8% to 2.1%), and living donor transplantation (1.2% versus 1.0%; difference, 0.1%; 95% confidence interval, -0.9% to 1.1%).

Conclusions Use of trained kidney transplant recipients as navigators did not increase first visits to a transplant center, waiting list placement, and receipt of deceased or living donor transplants.

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Introduction

Compared with long-term dialysis treatment, kidney transplantation generally offers a longer lifespan, better quality of life, and lower health care costs (1). Obtaining a kidney transplant requires patients to complete a series of steps, including medical suitability, interest in transplant, referral to a transplant center, first visit to center, transplant workup, successful candidate, waiting list or identify living donor, and receive transplant (2). Medical suitability refers to the absence of absolute contraindications to transplantation, such as a systemic infection or recent malignancy (3). The transplant center workup typically requires several visits and involves a medical history and physical examination, psychosocial assessment, evaluation and treatment of medical conditions, and laboratory studies (4). Patients who complete this workup and are found to be successful transplant candidates may be placed on a deceased

donor waiting list or may receive a kidney transplant from a living donor.

Many patients face barriers in completing the steps required to obtain a transplant (2). These barriers include inadequate assessment of medical suitability, lack of information about transplantation, reliance on nephrologists to make referrals to transplant centers, and difficulty completing the transplant center workup (2,5–10). We hypothesized that navigators may be able to help patients on hemodialysis complete these transplant process steps. Navigators are individuals who educate patients and help them navigate through the health care system (11). We reasoned that kidney transplant recipients may be ideal navigators for other patients because of a shared experience with ESKD. In addition, kidney transplant recipients have personal experience in completing the steps in the transplant process (12). In a previous study of 167

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patients in Cleveland, Ohio, we showed that patients on hemodialysis who received navigation over a period of 18–24 months completed more than twice as many steps as patients who received usual care. However, the sample size and follow-up duration of that study were not designed to determine the effect of navigators on the outcomes of waitlisting and transplantation (13). We now present the results of a larger study conducted in four cities to examine those outcomes.

Materials and Methods

Study Design

We conducted a cluster randomized, controlled trial involving 40 hemodialysis facilities and four transplant centers. In contrast to our previous work, this study was designed as a pragmatic trial to determine the effectiveness of navigators in routine clinical practice (13). As a result, we maximized the time available for navigators to interact with patients by not requiring them to collect detailed data on each patient. The study began on January 1, 2014 and was scheduled to continue until December 31, 2017. However, because of funding limitations, the study was completed on December 31, 2016. The study adheres to the Declarations of Helsinki and Istanbul, was approved by the institutional review boards of MetroHealth Medical Center (Cleveland, OH) and the other participating institutions, and was registered at ClinicalTrials.gov on November 11, 2013 (identifier NCT01981603).

Participants and Facilities

Transplant centers in Columbus, Ohio; Lexington, Kentucky; Louisville, Kentucky; and Fort Wayne, Indiana participated in the study. We focused on these cities, because they have only one adult transplant center. If there were two transplant centers in the same city, a navigator based at one center might encourage patients on dialysis to go to that transplant center at the expense of another center without necessarily increasing the total number of patients referred to transplant centers. We used a random number generator to select ten hemodialysis facilities that were located within 30 miles of each transplant center for a total of 40 facilities. We also used a random number generator to assign five facilities near each transplant center to an intervention group and the remaining five to a control group.

Intervention Group

Each transplant center hired a kidney transplant recipient to act as a navigator for patients on hemodialysis in the intervention group. Navigators underwent a 3-day training session in Cleveland, Ohio that included instructions on the kidney transplant process, medical records review, motivational interviewing, and human subjects protection. Navigators then approached adult patients during hemodialysis treatment at intervention facilities, informed them of the project, and obtained verbal consent to participate in the project. Navigators did not interact with patients who were identified by facility staff as mentally incompetent or non-English speaking. Patients ages 70 years old and older were also excluded, because relatively few transplants are performed in this group (1). On the basis of a review of medical records and questioning of patients, hemodialysis

facility staff, or transplant center staff, navigators determined the current step in the transplant process for each patient. On the basis of what the current step was, navigators carried out the tasks listed in Table 1.

Navigators generally met with participating patients monthly but could meet more or less frequently if they felt that to be more appropriate. They were also able to communicate with patients by phone. Quality control during the trial involved a combination of annual meetings, annual site visits, and regular telephone and email communication. Navigators attended an annual 2-day meeting in Cleveland to receive refresher training, review study progress, and jointly address any challenges. Two members of the Cleveland study team visited each study site annually to observe navigators, review their workflow, and meet with transplant center and dialysis facility staff. All navigators participated in twice-monthly conference calls with the Cleveland study team to review the progress of individual patients and formulate plans to address barriers to step completion. Navigators also submitted a weekly log summarizing the number of patients that they met with, the number of patients that they met with for the first time, up to three reasons for patients declining to participate that week, and up to three reasons for patients not moving forward in the transplant process that week.

Control Group

Control patients continued to receive care from their nephrologists and hemodialysis facilities. Navigators did not go to control facilities or interact with control patients.

Outcomes

Primary outcomes were (1) the proportion of adult patients who were on the waitlist on December 31 of the last year of the trial and (2) the proportion of adult patients who received a kidney transplant any time during the last year of the trial. An exploratory outcome was the proportion of adult patients who made a first visit to a transplant center in the last year of the trial. Patients ages 70 years old and older were excluded from both the numerator and denominator for these analyses. Data on waitlisting, deceased donor transplantation, and living donor transplantation were obtained from annual dialysis facility reports. These reports are produced under contract to the Centers for Medicare and Medicaid Services and include information on patient characteristics, treatment patterns, and access to transplantation (14). The reports for a particular year are generally available about 12 months later (*e.g.*, the 2016 reports were available in January 2018). In addition, the four participating transplant centers used their electronic medical record systems to provide annual counts of the number of patients who made a first visit to the transplant centers from each of the study hemodialysis facilities.

Statistical Analyses

We used means, SDs, and percentages to describe the characteristics of intervention and control facilities and patients at baseline (*i.e.*, before the trial). One of these characteristics, the standardized transplantation ratio (STR), had a skewed distribution, and therefore, we calculated the median and interquartile range instead. The STR is the ratio of the actual number of transplants at a hemodialysis facility divided by the expected number of patients after

Table 1. Tasks carried out by navigators at each step in the transplant process

Step	Tasks
Step 1. Suitability for referral to transplant center	Patients with absolute contraindications to kidney transplantation listed in their medical records were told why they were not candidates for transplantation
Step 2. Interest in transplantation	Patients were educated about the advantages and disadvantages of transplantation, the steps in the transplant process, and what to expect after transplantation. Navigators also shared their personal experiences with dialysis and transplantation
Step 3. Referral call to transplant center	Patients were encouraged to call the local transplant center even if they did not have a formal referral from their nephrologists. They were given the phone numbers of the transplant center, a list of the information that they might be asked to provide, and questions to ask
Step 4. First visit to transplant center	Patients were given directions to the transplant center, a list of things to take, and questions to ask. In addition, navigators explored transportation options for getting to the transplant center and reminded patients of upcoming appointments
Step 5. Transplant center workup	Navigators explained what to expect in a transplant center workup. Navigators also monitored completion of specific aspects of the workup, communicated with transplant center staff about outstanding tasks, and encouraged patients to complete the workup in a timely fashion
Step 6. Successful transplant candidate	Navigators served as an ongoing source of support and information. Navigators also educated patients about how to discuss living donation with potential donors
Step 7. On waiting list or evaluate potential living donor	Navigators served as an ongoing source of support and information. Navigators monitored patients' status on the waiting list and results of living donor evaluation

accounting for the demographic and medical characteristics of that facility's patients (15). The STR is typically calculated over a 3- or 4-year interval to provide more stable estimates. For each group (intervention or control), we determined the total number of outcomes (first visit to transplant center, waitlisting, deceased donor transplants, and living donor transplants) as a percentage of the total number of patients in 2013, the year before the trial started. We then determined the difference in these percentages between the two groups and corresponding 95% confidence intervals (95% CIs) and *P* values. As is the method in the dialysis facility reports, the denominator for these analyses was the total number of adult patients at the end of the year for waitlisting and the total number of patients at any time during the year for other outcomes. We used a similar approach to examine these transplant-related outcomes in 2016, the last year of the trial. To further examine the effect of navigation while accounting for baseline demographic and medical characteristics, clustering of patients within facilities, and possible correlations of responses at baseline and final time points, we performed a separate generalized estimating equations analysis with a logit link for each transplant-related outcome. Counts were assumed to be binomially distributed, and an unstructured working covariance matrix was used. In addition to the baseline characteristics listed in Table 2 (age, sex, race, ethnicity, cause of ESKD, duration of ESKD, facility number of patients, and facility STR), additional covariates included group assignment (intervention versus control), time (final versus baseline), and interaction (group by time). From the fit of this model, we obtained estimates and 95% CIs for covariate-adjusted odds ratios (*i.e.*, the odds of the outcome for intervention versus control at the baseline and final time periods) as well as the group by time interaction effect (corresponding to the ratio of these two odds ratios). All analyses were performed using JMP version 13.0 and SAS version 9.4, which are both from SAS Institute (Cary, NC).

On the basis of prior work, we estimated that about 18% of control patients would be waitlisted in the last year of the trial. To detect a higher waitlisting rate of 25% among

intervention patients would require 1074 total patients with a two-tailed α of 0.05 and 80% power. Similarly, we estimated that about 6% of control patients would receive a transplant in the last year of the trial. To detect a higher transplant rate of 10% among intervention patients would require 1438 patients.

Results

The characteristics of intervention and control group hemodialysis facilities were generally similar (Table 2). The mean patient age was 62–63 years old, about one third of patients were black, and the most common cause of ESKD was diabetes. The STR over the 3 years before starting the trial was similar between the two groups. Almost all of the participating dialysis facilities were for profit (90% in each group), and the mean number of social workers per facility was similar across groups (0.8 versus 0.7 full-time equivalents at intervention and control facilities, respectively).

At baseline, intervention and control groups were similar in the proportions of patients who made a first visit to a transplant center, were placed on a waiting list, and received a deceased or living donor transplant (Table 3). For example, 14.1% of patients in the intervention group made a first visit to a transplant center in 2013 compared with 11.8% of patients in the control group (difference, 2.3%; 95% CI, -0.8% to 5.3%). At the end of the trial, intervention and control groups were also similar in first visit, waitlisting, deceased donor transplantation, and living donor transplantation. For example, 4.0% of patients in the intervention group received a transplant in 2016 compared with 3.2% of patients in the control group (difference, 0.8%; 95% CI, -0.9% to 2.1%). In multivariable analyses, there were no statistically significant differences between the intervention group and the control group at the baseline or final time periods for any of the outcome variables (Table 4). In addition, the final-to-baseline ratio was not significantly different from 1.00, indicating that being in the intervention group did not result in improved

Table 2. Baseline characteristics of dialysis facilities and all adult patients participating in a pragmatic randomized, controlled trial of patient navigators

Characteristic	Intervention Group	Control Group
Facilities, <i>n</i>	20	20
Patients on December 31, 2013, <i>n</i> ^a	1014	885
Patients per facility, mean (SD)	51 (32)	44 (20)
Age, yr, mean (SD)	62 (3)	63 (4)
Women, <i>n</i> (%)	443 (44)	375 (42)
Race, <i>n</i> (%)		
White	622 (61)	579 (65)
Black	369 (36)	297 (34)
Other	23 (2)	9 (1)
Hispanic (%)	25 (2)	17 (2)
Cause of ESKD (%)		
Diabetes	444 (44)	400 (45)
Hypertension	279 (28)	247 (28)
GN	126 (12)	97 (11)
Other	165 (16)	141 (16)
Duration of ESKD, yr (%)		
<2.0	307 (30)	330 (37)
2.0–2.9	138 (14)	133 (15)
3.0–5.9	268 (26)	220 (25)
≥6.0	301 (30)	202 (23)
Standardized transplantation ratio for 2011–2013, median (interquartile range)	1.09 (0.66–2.51)	1.00 (0.44–1.39)

^aAll adult patients, including those age 70 years old and older.

outcomes in the final compared with the baseline period. For example, the odds ratio for first visit was 0.99 (95% CI, 0.56 to 1.76).

According to the entries in their logs, navigators identified a total of 869 patients who met our eligibility criteria. Of these, 545 agreed to meet with navigators, and 324 declined to participate. On average, navigators met with each participating patient 9.7 times. A review of navigator logs indicated that the most common reasons for declining to participate were lack of interest in transplantation (mentioned 114 times); medical limitations, such as heart disease (45 times); and feeling too old for a transplant (12 times). Review of logs also indicated that the most common reasons for not moving forward in the transplant process were medical limitations, such as obesity or smoking (mentioned 1278 times); nonadherence with medications or dialysis treatments (226 times); and financial concerns (177 times). Note that, because navigators met on multiple occasions with participating patients, an individual patient may be represented more than once in this analysis of reasons for not moving forward.

Discussion

We found that use of trained kidney transplant recipients as navigators did not increase first visits to a transplant center, waiting list placement, and receipt of deceased or living donor transplants. Although there were more patients who made a first visit to a transplant center by the end of the trial, these changes were similar among intervention and control groups. Strengths of this study include a rigorous randomized, controlled trial design, a large sample size, participation of transplant centers and hemodialysis facilities in four geographic areas, multiple interactions between

navigators and patients, a long follow-up duration, and use of Medicare data for key study outcomes. With the exception of ethnicity, subject characteristics were similar to those of patients on dialysis nationally (1). The small number of Hispanic subjects reflects the population of our region.

Previous randomized, controlled trials of navigators have often focused on cancer screening and treatment or patients who are high utilizers of health care services. These studies generally used nurses or lay health workers as navigators (not patients) (16,17). Systematic reviews of navigator interventions have found that such interventions have had mixed results (18,19). We hypothesized that kidney transplant recipients would be more effective as navigators, because they have already completed the steps in the transplant process. Other efforts to increase access to kidney transplantation include educating patients on dialysis about the option of transplantation, developing measures of transplant referral, streamlining the transplant workup, communicating with potential living donors, and disseminating data on rates of transplantation (15,20–24).

There are a number of potential explanations for the failure of navigation to significantly improve transplant-related outcomes. First, our previous work indicated that the benefit of navigators is most pronounced for patients who are at the early steps in the transplant process, such as suitability and interest (13). These early steps occur at dialysis facilities, which are where all in-person interactions between navigators and patients occurred. It is possible that navigators are less effective at helping patients with later steps in the transplant process (*i.e.*, those that occur at transplant centers and were the basis for our study outcomes [first visit, waitlisting, and transplantation]). This is supported by a recent trial that found that involvement of a transplant center–based navigator did not

Table 3. Primary outcomes (waitlisting and transplantation) and exploratory outcome (first visit) at the beginning and end of trial among patients under age 70 years old

Outcome	Intervention Group	Control Group	Difference (95% CI)	P Value
Baseline				
Patients under age 70 yr old in 2013, N	1041	836	—	—
Patients under age 70 yr old on December 31, 2013, N	765	629	—	—
Patients with first visit to transplant center in 2013, n/N	147/1041 (14.1%)	99/836 (11.8%)	2.3% (−0.8% to 5.3%)	0.15
Waitlisted patients on December 31, 2013, n/N	140/765 (18.3%)	118/629 (18.8%)	−0.5% (−4.6% to 3.6%)	0.83
Total transplants in 2013, n/N	53/1041 (5.1%)	29/836 (3.5%)	1.6% (−0.3% to 3.5%)	0.09
Deceased donor transplants in 2013, n/N	34/1041 (3.3%)	17/836 (2.0%)	1.2% (−0.3% to 2.7%)	0.10
Living donor transplants in 2013, n/N	19/1041 (1.8%)	12/836 (1.4%)	0.4% (−0.9% to 1.6%)	0.51
Final				
Patients under age 70 yr old in 2016, N	1026	959	—	—
Patients under age 70 yr old on December 31, 2016, N	754	716	—	—
Patients with first visit to transplant center in 2016, n/N	165/1026 (16.1%)	132/959 (13.8%)	2.3% (−0.8% to 5.5%)	0.15
Waitlisted patients on December 31, 2016, n/N	123/754 (16.3%)	99/716 (13.8%)	2.5% (−1.2% to 6.1%)	0.18
Total transplants in 2016, n/N	41/1026 (4.0%)	31/959 (3.2%)	0.8% (−0.9% to 2.4%)	0.36
Deceased donor transplants in 2016, n/N	29/1026 (2.8%)	21/959 (2.2%)	0.6% (−0.8% to 2.1%)	0.37
Living donor transplants in 2016, n/N	12/1026 (1.2%)	10/959 (1.0%)	0.1% (−0.9% to 1.1%)	0.79

95% CI, 95% confidence interval; —, not applicable.

significantly improve access to waitlisting among disadvantaged patients referred to a single transplant center. In that study, the navigator was a transplant social worker and made an average of about nine contacts with each patient (25). Moreover, the new waiting list allocation system, which counts time from start of dialysis rather than from listing, may make efficient workups less important (26). Second, many patients at the participating hemodialysis facilities were ineligible or declined to participate. This may have decreased our ability to observe a benefit from navigation, because we looked at outcomes across all patients under age 70 years old, regardless of whether they interacted with navigators. This lack of participation may also limit the generalizability of our findings. Third, the participating dialysis facilities may have already done a good job at helping suitable and interested patients through the transplant process, and therefore, the incremental value of navigation was small. Fourth, the navigators were supervised from afar instead of in person as in

our previous work. This may have limited our ability to identify and address challenges. Because we did not collect detailed process data in this pragmatic trial, it is not possible to determine which explanations are most likely.

Several limitations must be considered in interpreting our results. The study was terminated 1 year early because of funding limitations and may have been underpowered as a result. Even without the early termination, the study duration may have been insufficient to determine an effect on deceased donor transplantation given that the median waiting time for a deceased donor kidney is 4 years (1). We did not independently check the accuracy of first visit, waitlisting, or transplant data. We did not collect patient-level data on comorbid conditions, socioeconomic status, interactions with navigators, completion of specific steps, or satisfaction with transplant-related decision making. In our conference calls, navigators frequently mentioned patients who were medically suitable and interested but did not move forward despite multiple interactions with

Table 4. Multivariable analysis of primary outcomes (waitlisting and transplantation) and exploratory outcome (first visit)

Outcome ^a	Odds Ratio, Intervention versus Control (95% CI)		
	Baseline	Final	Final/Baseline
First visit to transplant center	1.17 (0.72 to 1.89)	1.16 (0.69 to 1.96)	0.99 (0.56 to 1.76)
Waitlisting	0.72 (0.49 to 1.06)	0.90 (0.66 to 1.24)	1.26 (0.80 to 1.97)
Any transplant	0.92 (0.56 to 1.52)	0.76 (0.40 to 1.48)	0.83 (0.38 to 1.82)
Deceased donor transplant	1.02 (0.53 to 1.97)	0.80 (0.35 to 1.84)	0.79 (0.28 to 2.22)
Living donor transplant	0.63 (0.27 to 1.47)	0.54 (0.17 to 1.68)	0.86 (0.29 to 2.58)

95% CI, 95% confidence interval.
^aBaseline covariates were adjusted for age, sex, race, ethnicity, cause of ESKD, duration of ESKD, facility number of patients, and facility standardized transplantation ratio.

navigators over a long period of time. These patients kept coming up with excuses to delay making a referral call or a first visit. Further work is needed to understand and address the reluctance among this group of patients.

In conclusion, use of trained kidney transplant recipients as navigators did not increase first visits to a transplant center, waiting list placement, and receipt of deceased or living donor transplants. Other approaches are needed to improve access to transplantation. We believe that such approaches should still focus on the transplant process steps, because these eight sequential steps must be completed to receive a transplant. It is worth noting that increasing the number of individuals receiving living donor transplants will increase the number of transplants performed. However, increasing the number of individuals on the deceased donor waiting list will not increase the total number of transplants performed. As a result, continued efforts to increase organ donation are also necessary.

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Disclosures

None.

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