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Impact of Medicare Coverage on Disparities in Access to Simultaneous Pancreas and Kidney Transplantation

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Abstract

In the setting of disparities in access to simultaneous pancreas and kidney transplantation (SPKT), Medicare coverage for this procedure was initiated July 1999. The impact of this change has not yet been studied. A national cohort of 22 190 type 1 diabetic candidates aged 18–55 for kidney transplantation (KT) alone or SPKT was analyzed. Before Medicare coverage, 57% of Caucasian, 36% of African American and 38% of Hispanic type 1 diabetics were registered for SPKT versus KT alone. After Medicare coverage, these proportions increased to 68%, 45% and 43%, respectively. The overall increase in SPKT registration rate was 27% (95% CI 1.16–1.38). As expected, the increase was more substantial in patients with Medicare primary insurance than those with private insurance (Relative Rate 1.18, 95% CI 1.09–1.28). However, racial disparities were unaffected by this policy change (African American vs. Caucasian: 0.97, 95% CI 0.87–1.09; Hispanic vs. Caucasian: 0.94, 95% CI 0.78–1.05). Even after Medicare coverage, African Americans and Hispanics had almost 30% lower SPKT registration rates than their Caucasian counterparts (95% CI 0.66–0.79 and 0.59–0.80, respectively). Medicare coverage for SPKT succeeded in increasing access for patients with Medicare, but did not affect the substantial racial disparities in access to this procedure.

Keywords

Access to transplantation; pancreas transplantation; Simultaneous pancreas and kidney transplantation (SPKT)

Introduction

The incidence of type 1 diabetes, a common cause of end-stage renal disease (ESRD) (1), has been rising steadily in the United States (2). Studies have consistently shown that simultaneous pancreas and kidney transplantation (SPKT) is the best treatment for patients with both type 1 diabetes and ESRD, offering a significant survival advantage over kidney transplant (KT) alone (3–11). Significant improvements in diabetic neuropathy, gastropathy and vasculopathy have been demonstrated following SPKT (3–9), and it is the only method of reliably maintaining euglycemia (12). Long-term outcomes are excellent, with a 45%

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lower risk of death 10 years following SPKT compared to KT (13). Furthermore, the current allocation system favors combined allocation of pancreas and kidney, so that patients registered for SPKT have significantly shorter median waiting times (295–855 days, varying by blood type) than those registered for KT (597–1763 days, varying by blood type) (14), a huge advantage given the 33% 5-year dialysis survival rate in patients whose primary cause of ESRD is diabetes (15). SPKT priority also results in allocation of much higher quality kidneys to SPKT recipients than to KT alone recipients, as the average SPKT donor is much younger and has fewer comorbidities than the average KT donor.

The incidence of ESRD in African Americans with type 1 diabetes (400 cases per million) is significantly higher than in Caucasians (117 cases per million) (16–18). Historically, studies showed pronounced racial disparities in access to SPKT, with African Americans with type 1 diabetes and ESRD who are registered for transplantation significantly less likely to be registered for SPKT, the optimal treatment option (19). Although African American ESRD patients were less likely to be referred for transplantation and less likely to be placed on the waitlist once referred, the disparity in SPKT versus KT affected even those African Americans who got referred and listed (20,21). Furthermore, although African Americans were much less likely than Caucasians to receive a kidney once registered for KT, this racial gap in waiting time was significantly narrowed in patients awaiting SPKT. Finally, while some studies indicated that cultural reluctance toward transplantation (22–24) and increased numbers of comorbid conditions (20,21,25,26) may partially contribute to racial disparities in access to KT, these barriers could not explain the disparity in access to SPKT because it existed among patients who had already been referred and deemed appropriate for transplantation.

Providing health insurance coverage has been successful in reducing disparities in access to various healthcare services (27) and reducing disparities in overall health status (28). In July 1999, insurance coverage for SPKT was made available through Medicare to all potential recipients (patients with type 1 diabetes and ESRD) (29–31). To date, no studies have explored the effect of this change in Medicare coverage on access to SPKT overall and access to SPKT among ethnic/racial minorities. In a national study, we examined whether the change in Medicare coverage was associated with an increase in overall SPKT candidate registrations, and whether it ameliorated ethnic/racial disparities in access to SPKT.

Materials and Methods

The study population was drawn from a national prospective cohort of 22 190 US patients aged 18 to 55 with type 1 diabetes who were candidates for a primary deceased donor KT or SPKT between January 1, 1995, and February 1, 2008, using data from the United Network for Organ Sharing (UNOS). Candidates (one observation per patient) rather than registrations (possibly multiple observations per patient) were studied. Of these patients, 9015 first registered prior to and 13 175 first registered after January 1, 2000. Patients who received a live donor kidney transplant within 90 days of registration were excluded. Patients who registered for an SPKT within 90 days of registering for a KT were considered to have registered for an SPKT. Patients were considered to have type 1 diabetes if this was listed as their primary reason for renal failure, secondary reason for renal failure or if the type 1 diabetes comorbidity was selected on the UNOS candidate form.

This study evaluated the association between patient characteristics and relative rate (RR) of registering for SPKT as compared with registering for KT, before and after Medicare coverage for SPKT. Although Medicare coverage began July 1999, we stratified at January 2000 to allow this change in coverage to change practice patterns. The Johns Hopkins

Institutional Review Board reviewed this study and determined that it qualified for an exemption under 45 CFR 46.101(b).

The following independent variables were analyzed: race/ethnicity, age at registration, body mass index (BMI) at registration, blood type, panelreactive antibody level (PRA), gender, primary insurance, education and hypertension. The appropriate functional form of these variables was determined by exploratory data analysis in unadjusted models. Race/ethnicity was defined as that which was reported by each candidate's transplant center to UNOS using the Transplant Candidate Registration form, and was categorized as Caucasian (68.5%), African American (18.3%), Hispanic (10.0%) or other (3.2%). Because all factors that were investigated were biologically plausible confounders, forced multivariate models were used. Absence of colinearity among the covariates was confirmed by testing variance inflation factors. Values were missing for 19% of education, 16% of PRA, 13% of hypertension, 3% of BMI and less than 1% for all other covariates. Missing values were imputed with five rounds of multiple imputation using ICE for Stata (32). To ensure that our inferences were not sensitive to imputed values, coefficients from imputed models were compared with those from models where missing values were handled using case wise deletion, and similar inferences were noted.

Relative risk of registering for SPKT versus KT was analyzed using generalized linear models (33). For the purposes of describing registration practices, relative risks are interpreted as RRs in this manuscript. To account for correlations in practice protocols, disease severity and organ availability among transplant centers, variance estimates were adjusted for center-level clustering in all models. Unless otherwise specified, all tests were two-sided with statistical significance set at $\alpha = 0.05$. All analyses were performed using Stata 10.0/MP for Linux (StataCorp., College Station, TX).

Results

Between 1995 and 1999, of patients with type 1 diabetes and ESRD registered for either KT or SPKT, 74.1% were Caucasian, 15.6% were African American and 7.7% were Hispanic (Table 1). Of patients with type 1 diabetes and ESRD registered for either KT or SPKT since 2000, 20.2% were African American and 11.6% were Hispanic. Furthermore, we observed that more older patients with type 1 diabetes and ESRD were registering for transplantation, with an increase from 11.5% to 18.8% of registrants aged 50–55.

Although it is important for a patient with type 1 diabetes and ESRD to register for at least a kidney transplant, SPKT registration is associated with better organ offers, faster rates of transplantation and better long-term outcomes than KT registration alone. Between 1995 and 1999, we observed two major disparities in access to SPKT for patients with type 1 diabetes and ESRD who were registered for transplantation. First was insurance coverage, with only 42.1% of Medicare patients and 43.8% of Medicaid patients registered for SPKT, compared with 61.2% of privately insured patients. Second was race, with only 36.2% of African Americans and 38.0% of Hispanics registered for SPKT, compared with 57.1% of Caucasians.

After January 1, 2000, a greater proportion of all patients with type 1 diabetes and ESRD were registered for SPKT versus KT. Insurance disparities were reduced, with 53.7% of Medicare patients and 53.8% of Medicaid patients registered for SPKT compared with 65.3% of privately insured patients. However, racial disparities remained unchanged, with 44.8% of African Americans and 42.9% of Hispanics registered for SPKT as compared with 68.2% of Caucasians.

These observations were confirmed in multivariate models adjusting for other factors that might determine eligibility for or access to SPKT. Stratified regression models are shown in Table 2, with one model demonstrating factors associated with SPKT before 2000 (columns 2 and 3) and a separate model demonstrating factors associated with SPKT after 2000 (columns 4 and 5). An interaction term analysis is shown in Table 3, where all observations were included, with terms for the main effect of time (representing the change in Medicare coverage), the main effects of patient factors as well as the interaction between Medicare coverage and patient factors.

In general, 27% more patients with type 1 diabetes and ESRD who registered for a transplant were listed for SPKT since 2000 (95% CI 1.16–1.38, $p < 0.001$). Interestingly, college education was an important factor affecting SPKT registration before 2000 (RR 1.13, 95% CI 1.07–1.19, $p < 0.001$) and after 2000 (RR 1.07, 95% CI 1.03–1.11, $p < 0.001$) with an interaction term demonstrating no reduction in the importance of this factor (RR 0.95, 95% CI 0.89–1.01, $p = 0.1$).

As expected, Medicare coverage for SPKT significantly lessened the Medicare coverage barrier to this procedure. Before 2000, Medicare patients were 29% less likely (95% CI 0.66–0.77, $p < 0.001$) than privately insured patients to be registered for SPKT. After 2000, Medicare patients were only 16% less likely (95% CI 0.79–0.89, $p < 0.001$) than privately insured patients. Interaction term analysis shows that registration rates for SPKT versus KT increased for Medicare patients by 18% more than they increased for privately insured patients (95% CI 1.09–1.28, $p < 0.001$). For Medicaid patients, although stratified models suggested an increase in registration rates for SPKT versus KT, interaction term analysis showed no statistically significant change in SPKT registration rates when compared with privately insured patients (95% CI 0.97–1.26, $p = 0.1$).

Unfortunately, Medicare coverage for SPKT had no statistically significant effect on racial disparities in access to this procedure. Before 2000, African Americans registering for a transplant were 27% less likely (95% CI 0.65–0.83, $p < 0.001$) and Hispanics were 25% less likely (95% CI 0.63–0.90, $p < 0.001$) than Caucasians to be registered for SPKT. After 2000, African Americans were still 28% less likely (95% CI 0.66–0.79, $p < 0.001$) and Hispanics 31% less likely (95% CI 0.59–0.80, $p < 0.001$) than Caucasians to be registered for SPKT. Interaction term analysis shows that registration rates for SPKT versus KT did not increase any more for African Americans (95% CI 0.87–1.09, $p = 0.6$) or Hispanics (95% CI 0.78–1.05, $p = 0.2$) than they did for Caucasians.

To examine if this effect varied by geographic region, the full interaction term model (shown in Table 3) was repeated for each UNOS region. Although we caution that significant reduction of sample size reduced the power to detect differences that were seen in the full cohort, we did indeed see differences in the African American disparity in access to SPKT by region, even after adjusting for all relevant confounders listed in Table 3. Disparities ranged from 58% less access to SPKT for African Americans in Region 9 to no disparity in Region 1 (Table 4, left column). However, in general, it seemed that almost every region (10/11 by point estimate, 8/11 that were statistically significant) demonstrated disparities in access to SPKT for African Americans. Also consistent between regions was our inability to detect a statistically significant difference in the change in disparities for African Americans associated with the change in Medicare coverage, similar to the effect that was seen nationally (Table 4, right column). Only in one region (Region 5) was there a remarkable trend toward improved access to SPKT for African Americans (RR 1.37, 95% CI 0.97–1.94, $p = 0.07$).

Discussion

In this national study of transplant candidates, we found that addition of Medicare coverage for SPKT after July 1999 was associated with an increase in registration rates for SPKT among Medicare patients, suggesting that the change did result in increased access overall. However, even after adjusting for factors that might confound suitability for or access to SPKT, there was no statistically significant change in racial disparities in access to SPKT.

It has previously been postulated that insurance coverage for SPKT might increase overall access to this highly beneficial procedure and reduce or eliminate racial disparities in access (19). Our analysis of national data shows evidence that the former was accomplished, but not the latter, suggesting that the underlying mechanism for ethnic/racial disparities in access to SPKT is not differential insurance coverage as previously hypothesized (16,19).

An alternative hypothesis for the persistent racial disparity is bias in provider referrals. Historically, African Americans have had lower posttransplant survival rates than their Caucasian counterparts. Although studies have shown this is not the case in SPKT and that African Americans derive equal benefits from the procedure, it is possible that historic perceptions of worse outcomes for this subgroup (34,35) have led to provider reluctance to register these patients for the more complex combined operation that carries higher rates of up-front risks (36). It is also possible that the disparity is occurring at the level of the patient, with African American or Hispanic patients less willing to register for SPKT compared to KT, and might represent a lack of knowledge among patients in these subgroups about improved outcomes, shorter waiting times and higher quality organ offers for SPKT registrants. Further studies are needed to assess the contributions of provider practice patterns and patient preferences to ethnic/racial disparities in access to SPKT.

We acknowledge a number of limitations in our study. As a study of the national transplant registry, race is reported by transplant centers and categorized by UNOS, and our inferences would be subject to bias if the proclivity for misreporting African American or Hispanic race/ethnicity was associated with registration for KT alone. Additionally, diagnosis of type 1 diabetes is also reported by transplant centers, and our inferences would be subject to bias if the proclivity of misreporting type 2 diabetics were associated with race. To minimize such a misclassification bias, we adjusted for BMI in all regression models, so that if African Americans were more likely to be obese, and those who were obese were more likely to have type 2 diabetes that was misclassified as type 1 in the registry and thus less likely to be listed for SPKT, this would be accounted for in the models. We also performed a sensitivity analysis where all analyses were repeated in a subcohort limited only to patients with BMI <30, to avoid the possibility that patients with BMI >30 had type 2 diabetes misclassified as type 1. All inferences in this sensitivity analysis were consistent with the results reported in this article, particularly that African American and Hispanic patients in the BMI <30 subcohort had >20% lower access to SPKT than Caucasian patients, and this disparity did not change with the initiation of Medicare coverage for SPKT.

We are limited to the assumption that missing data are missing at random, although our sensitivity analyses comparing multiple imputation with casewise deletion indeed suggest that our inferences were not sensitive to our choice of handling for missing data. Also, we did not have data on household income, and as such we had to rely on surrogates such as insurance status and education level. It is possible that African American and Hispanic households were more likely to have lower income levels and that those with lower incomes were less likely to register for SPKT; this would not have changed our observations about the disparity but might have helped explain it. Finally, our study is observational and as such

we can only demonstrate associations, not causal relationships, between Medicare insurance coverage and changes in SPKT registration.

While Medicare coverage for SPKT appears to have increased registration for this procedure among Medicare patients, it has not reduced racial disparities in access to this procedure. Despite the fact that type 1 diabetes disproportionately affects minority communities and disproportionately results in ESRD among members of these communities, disturbing disparities in access to this beneficial treatment modality persist. More research is needed to elucidate the underlying causes for these disparities so that appropriate interventions can be developed to ensure equitable access.

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Table 1

Characteristics of adults with type 1 diabetes and ESRD registered for KT or SPKT, prior to (1/95–12/99) or after (1/00–2/08) Medicare coverage for SPKT

	1/95–12/99	1/00–2/08
Race		
Caucasian	74.1%	64.7%
African American	15.6%	20.2%
Hispanic	7.7%	11.6%
Gender		
Male	57.8%	58.8%
Female	42.2%	41.2%
Insurance		
Private	47.2%	47.9%
Medicare	42.4%	40.2%
Medicaid	7.8%	9.3%
Education		
Precollege	50.6%	52.2%
College	49.4%	47.8%
Blood type		
A	36.7%	35.8%
B	11.2%	12.7%
AB	3.8%	3.7%
O	48.2%	47.8%
Peak PRA		
0–19%	85.4%	84.2%
20–79%	9.0%	10.1%
>80%	5.5%	5.7%
BMI at listing		
<25	60.9%	47.9%
25–30	27.2%	31.5%
30–35	8.5%	14.6%
>35	3.4%	6.1%
Age at listing		
18–39	52.4%	43.1%
40–49	36.0%	38.1%
50–55	11.5%	18.8%
Hypertension	81.5%	84.4%

Table 2

Relative rate of registration for SPKT versus KT, prior to (1/95–12/99) and after (1/00–2/08) Medicare coverage for SPKT

	1/95–12/99		1/00–2/08	
	RR (95% CI)	**p-Value**	**RR (95% CI)**	**p-Value**
Race				
Caucasian	Reference		Reference	
African American	**0.73 (0.65–0.83)**	**<0.001**	**0.72 (0.66–0.79)**	**<0.001**
Hispanic	**0.75 (0.63–0.90)**	**<0.001**	**0.69 (0.59–0.80)**	**<0.001**
Gender				
Male	Reference		Reference	
Female	0.97 (0.94–1.01)	0.2	0.97 (0.95–1.00)	0.05
Insurance				
Private	Reference		Reference	
Medicare	**0.71 (0.66–0.77)**	**<0.001**	**0.84 (0.79–0.89)**	**<0.001**
Medicaid	**0.74 (0.65–0.85)**	**<0.001**	**0.83 (0.76–0.90)**	**<0.001**
Education				
Pre-college	Reference		Reference	
College	**1.13 (1.07–1.19)**	**<0.001**	**1.07 (1.03–1.11)**	**<0.001**
Blood type				
A	Reference		Reference	
B	1.03 (0.96–1.10)	0.4	0.98 (0.94–1.03)	0.5
AB	1.01 (0.92–1.12)	0.8	1.02 (0.96–1.09)	0.5
O	1.03 (0.99–1.07)	0.2	1.00 (0.98–1.03)	0.9
Peak PRA				
0–19%	Reference		Reference	
20–79%	0.95 (0.87–1.04)	0.2	0.92 (0.86–0.98)	0.01
>80%	0.88 (0.76–1.02)	0.1	0.94 (0.86–1.02)	0.1
BMI				
<25	Reference		Reference	
25–30	0.96 (0.92–1.01)	0.1	0.91 (0.88–0.95)	<0.001
30–35	0.71 (0.63–0.80)	<0.001	0.66 (0.60–0.72)	<0.001
>35	0.53 (0.42–0.67)	<0.001	0.35 (0.28–0.44)	<0.001
Age at listing				
18–39	Reference		Reference	
40–49	0.80 (0.76–0.85)	<0.001	0.82 (0.78–0.85)	<0.001
50–55	0.43 (0.37–0.51)	<0.001	0.50 (0.45–0.56)	<0.001
Hypertension	0.94 (0.87–1.02)	0.1	0.98 (0.93–1.04)	0.5

Table 3

Effect of Medicare coverage for SPKT on the role of other patient characteristics in determining registration for SPKT versus KT

	Main effect		Interaction term	
	RR (95% CI)	**p-Value**	**RR (95% CI)**	**p-Value**
Coverage era				
1/95–12/99	Reference			
1/00–2/08	1.27 (1.16–1.38)	<0.001		
Race				
Caucasian	Reference		Reference	
African American	**0.74 (0.65–0.83)**	**<0.001**	**0.97 (0.87–1.09)**	**0.6**
Hispanic	**0.76 (0.63–0.91)**	**<0.001**	**0.94 (0.78–1.05)**	**0.2**
Gender				
Male	Reference		Reference	
Female	0.98 (0.94–1.01)	0.2	1.00 (0.94–1.05)	0.9
Insurance				
Private	Reference		Reference	
Medicare	**0.71 (0.66–0.77)**	**<0.001**	**1.18 (1.09–1.28)**	**<0.001**
Medicaid	**0.75 (0.65–0.80)**	**<0.001**	**1.11 (0.97–1.26)**	**0.1**
Education				
Pre-college	Reference		Reference	
College	**1.13 (1.07–1.19)**	**<0.001**	**0.95 (0.89–1.01)**	**0.1**
Blood type				
A	Reference			
B	1.00 (0.96–1.04)	0.9		
AB	1.02 (0.96–1.08)	0.5		
O	1.01 (0.99–1.03)	0.3		
Peak PRA				
0–19%	Reference			
20–79%	0.93 (0.88–0.98)	<0.001		
>80%	0.92 (0.85–0.99)	0.02		
BMI				
<25	Reference			
25–30	0.93 (0.90–0.96)	<0.001		
30–35	0.67 (0.62–0.73)	<0.001		
>35	0.40 (0.33–0.48)	<0.001		
Age at listing				
18–39	Reference			
40–49	0.81 (0.79–0.84)	<0.001		
50–55	0.48 (0.43–0.54)	<0.001		
Hypertension	0.96 (0.92–1.02)	0.2		

Table 4

Effect of Medicare coverage for SPKT on the role of African American race in determining registration for SPKT versus KT, stratified by region

	Main effect		Interaction term	
UNOS Region #	RR (95% CI)	p-Value	RR (95% CI)	p-Value
1	1.05 (0.35–3.21)	0.9	0.77 (0.28–2.10)	0.6
2	0.79 (0.64–0.96)	0.02	0.99 (0.86–1.14)	0.9
3	0.87 (0.55–1.38)	0.6	0.76 (0.47–1.23)	0.3
4	0.62 (0.39–0.99)	0.05	0.86 (0.54–1.39)	0.6
5	0.61 (0.43–0.85)	<0.001	1.37 (0.97–1.94)	0.07
6	0.69 (0.56–0.86)	<0.001	1.10 (0.76–1.59)	0.6
7	0.88 (0.77–1.01)	0.07	1.01 (0.88–1.15)	0.9
8	0.59 (0.36–0.99)	0.05	1.15 (0.74–1.79)	0.5
9	0.42 (0.21–0.84)	0.01	1.08 (0.55–2.11)	0.8
10	0.58 (0.45–0.74)	<0.001	1.26 (0.95–1.66)	0.1
11	0.72 (0.59–0.87)	<0.001	1.05 (0.92–1.21)	0.5
All	0.74 (0.65–0.83)	<0.001	0.97 (0.87–1.09)	0.6