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Original Article

Impact of donor kidney biopsy on kidney yield and posttransplant outcomes

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ABSTRACT

Procurement biopsy is performed to determine kidney quality, but evidence supporting such association is poor. We investigated the impact of glomerulosclerosis percentage (GS%) on kidney yield and patient outcomes. Information on deceased kidney donors from July 1, 2017, to June 30, 2019, was collected. Association between GS% and kidney yield (number of kidneys procured per donor) and posttransplant graft and patient outcomes were studied. Maximal GS% and minimal GS% were calculated to determine the relationship between GS% and kidney yield; minimal GS% only for correlation with posttransplant outcomes. Multinomial logistic regression and Cox models with least absolute shrinkage and selection operator were used to analyze the association of GS% with kidney yield and posttransplant outcomes, respectively. The kidney yield was 1.63 when maximal GS% and minimal GS% were <5%, but was 0.88 when both GS% were >20%. The hazard ratio for graft failure 1 year after transplant was 1.05 when minimal GS% was 16% to 20%, but was 1.3 for GS% of >20%. The hazard ratio for mortality increased from 1 to 1.2 when minimal GS% reached >20%. In summary, higher GS% was associated with lower kidney yield and inferior posttransplant outcomes. Incorporation of GS% into Scientific Registry of Transplant Recipients models may reassure organ procurement organizations and transplant centers pursuing kidneys with relatively high GS% levels, thereby reducing kidney discard rates.

Introduction

The quality of deceased donor kidneys, measured by clinical metrics such as the Kidney Donor Risk Index (KDRI),[1] is associated with graft survival. However, the potential association of histological metrics, which are not included in the KDRI, with outcomes is uncertain.[2] Nevertheless, kidney glomerulosclerosis (GS), typically assessed by biopsy at the time of procurement, is widely perceived to predict graft outcomes.[3,4] As a result, procurement biopsies are commonly performed by organ procurement organizations (OPOs) in the United States[5] to guide both organ recovery by OPOs and utilization by transplant centers.

As the gap between organ need and organ availability for kidneys continues to grow, a major societal goal is to maximize organ utilization with organs traditionally considered "marginal."[6,7] Because even marginal kidneys confer a survival benefit compared with remaining on dialysis,[8,9] many kidneys with suboptimal findings on biopsy are likely suitable for transplant. The challenge for OPOs is to balance the mission of maximizing organ yield with the quality of the organs recovered. Transplant programs must weigh the benefits of increased transplant volume, reduced wait time, and lower waitlist mortality against the risks of inferior graft and patient survival outcomes. As a result, OPOs, which are evaluated on organ yield (defined as the number of organs utilized per donor), and transplant programs, which are evaluated on long-term posttransplant outcomes, may be reluctant to use kidneys with significant levels of GS percentage (%). However, OPOs and transplant centers might be more incentivized to use such kidneys if procurement biopsy findings were explicitly accounted for in the OPO-specific report (OSR) and program-specific report (PSR) ("outcome") models.[10,11]

To investigate how incorporation of kidney biopsy information might affect yield and posttransplant outcome models, we estimated the effect of donor kidney histology on cohorts for recent OSRs and PSRs. We hypothesized that GS% would be associated with yield and posttransplant

Abbreviations: GS, glomerulosclerosis; HR, hazard ratio; KDRI, Kidney Donor Risk Index; OPO, organ procurement organization; OPTN, Organ Procurement and Transplantation Network; OSR, OPO-specific report; PSR, program-specific report; SRTR, Scientific Registry of Transplant Recipients.

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outcomes. If so, this would suggest that incorporation of histologic information into the risk-adjusted models for the OSRs and PSRs could incentivize pursuing marginal donors and organs while ensuring that OPOs and transplant programs are fairly judged.

Methods

Data sources and study cohort

This study used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by the members of the Organ Procurement and Transplantation Network (OPTN), and has been described elsewhere.[12] The Health Resources and Services Administration (HRSA), US Department of Health and Human Services, provides oversight of the activities of the OPTN and SRTR contractors. With regard to the collection and reporting of demographic data on race and ethnicity, race is self-reported and therefore classified as Asian, Black, Native American, White, and other, as per the Office of Management and Budget standards. For the model of kidney yield (described below), we used cohorts from SRTR OSRs (https://www.srtr.org/reports/opo-specific-reports/). We included all 21 559 deceased kidney donors from July 1, 2017, to June 30, 2019, of whom 11 071 had 1 or 2 kidneys biopsied and 10 488 had neither kidney biopsied. A total of 32 109 deceased donor kidneys were transplanted, and 11 009 kidneys were discarded.

For models of patient outcomes, we used a cohort from SRTR PSRs, which typically exclude multiorgan transplants and pediatric recipients (https://www.srtr.org/reports/program-specific-reports/). The cohort consisted of all deceased donor kidney transplant recipients from January 1, 2016, to June 30, 2018. During this period, 30 984 recipients received 32 109 kidneys, of which 15 865 were biopsied.

This research conforms to the US Federal Policy for the Protection of Human Subjects. The study was conducted as secondary research on data collected on behalf of the United States Federal Government, and as such is not considered research on human subjects.

Covariates

Covariates used for risk adjustment were those that are likely to associate with the outcomes. For organ yield models, donor risk factors were age, sex, race, height, weight, body mass index, cause of death, creatinine value at the time of death of the donor, history of diabetes and hypertension, hepatitis C status, donation after cardiac death, KDRI score, and the circumstance of death (https://srtr.org/tools/deceased-donor-yield/). For posttransplant outcome models, risk factors were age, sex, race, weight, body mass index, calculated panel-reactive antibodies, dialysis duration (ie, vintage), cause of end-stage kidney disease, age, KDRI score, history of diabetes and hypertension, donor cardiac death status, terminal creatinine value, local vs national share status, cold ischemia time, and degree of human leukocyte antigen (HLA) mismatch for donors (https://srtr.org/tools/posttransplant-outcomes/).

Outcomes

Outcomes studied were organ yield in the OSR models (number of kidneys used per donor) and posttransplant patient and graft (kidney) survival in the PSR models. The OSR model is a multinomial logistic regression model that estimates the relative risk of yielding 0, 1, or 2 kidneys. The multinomial regression model here is a bit different than a standard multinomial regression one—there is no fixed reference number of kidneys. For example, the coefficients for 2 kidneys are relative risks of placing 2 kidneys without any comparison to the placement of 0 or 1 kidney. Similarly, the coefficients for 1 kidney are relative risks of placing 1 kidney without any comparison to the placement of 0 or 2 kidneys.

Statistical analysis

The least absolute shrinkage and selection operator (LASSO) was used to estimate the association of GS% in risk-adjusted multinomial logistic models of kidney yield and Cox proportional hazard models of 1-year graft survival and 1-year patient survival. The LASSO shrinks the effects of model covariates toward 0, giving effects of 0 to risk factors with the smallest associations with the outcome. The amount of shrinkage and the number of covariates without an effect in the LASSO are determined by minimizing crossvalidated predicted error.

In most cases, 2 kidneys from 1 donor were biopsied, yielding minimal GS% and maximal GS%; both minimal and maximal GS% were included in the model of organ yield. Organ yield, defined as the average number of kidneys transplanted per donor, was estimated in a counterfactual framework. In other words, the average number of kidneys was estimated if each donor had the given combination of minimal and maximal GS%. By contrast, in case of en bloc transplants, only minimal GS% was included in the models of posttransplant graft survival and patient survival because these outcomes depended on the performance of the "better kidney"—the kidney with minimal GS%. For single kidney transplants, only one GS% was available per kidney and the GS% of that kidney was used in the model. We plotted the correlation of the OSR and PSR models with and without GS% to assess whether the addition of GS% improves the model performance.

Results

Characteristics of the cohorts

For the model of the association of degree of GS% with kidney yield, characteristics of donors are listed in Table 1.

Among donors with biopsied kidneys, 5912 donors had a maximal GS % of 0% to 5%, 1978 had a maximal GS% of 6% to 10%, 1652 had a maximal GS% of 11% to 20%, and 1529 had a maximal GS% of >20%. In terms of minimal GS, 7830 donors had a minimal GS% of 0% to 5%, 1486

Table 1
Demographic characteristics (yield models).

Donor characteristic	Value (N = 21 559)
Age, mean ± SD (y)	41 ± 17
Male sex	60.5%
Race	
Asian	2.5%
Black	16.2%
Native American	0.7%
White	79.8%
Other	0.8%
Height, mean ± SD (cm)	168 ± 19
Weight, mean ± SD (kg)	81 ± 26
BMI, mean ± SD[a]	28 ± 7
Cause of death	
Anoxia	43.2%
Trauma	27.2%
CVA/stroke	26.5%
Other	3.%
Terminal creatinine, mean ± SD, mg/dL	1.64 ± 1.77
History of diabetes mellitus	12.8%
History of hypertension	35.4%
Hepatitis C positivity	5.6%
DCD	20.1%
KDRI score, mean ± SD	1.40 ± 0.54
Circumstances of death	
Homicide	4.2%
Natural cause	43.8%
Suicide	10.1%
Motor vehicle crash	13.2%
Other	28.7%

BMI, body mass index; CVA, cerebrovascular accident; DCD, donation after cardiac death; KDRI, Kidney Donor Risk Index.
[a] Calculated as weight in kilograms divided by height in meters squared.

Table 2
Level of GS% in donors with biopsied kidneys (yield models).[a]

Minimal GS%	Maximal GS%				
	NA/UNK	0%-5%	6%-10%	11%-20%	>20%
NA/UNK	10 488 (48.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
0%-5%		5912 (27.4%)	1325 (6.1%)	443 (2.1%)	150 (0.7%)
6%-10%			653 (3.0%)	661 (3.1%)	172 (0.8%)
11%-20%				548 (2.5%)	465 (2.2%)
>20%					742 (3.4%)

GS, glomerulosclerosis; NA, not applicable; UNK, unknown.
[a] N = 21 559.

had a minimal GS% of 6% to 10%, 1013 had a minimal GS% of 11% to 20%, and 742% had a minimal GS% of >20% (Table 2).

For the assessment of GS% on graft and recipient survival in PSR models, a total of 32 109 deceased kidneys were transplanted into 30 985 recipients from January 1, 2016, to June 30, 2018, of which 15 865 were biopsied. Characteristics are listed in Table 3.

Among the recipients who received the biopsied kidneys, 11 607 recipients received kidneys with a maximal GS% of 0% to 5%, 2439 recipients received kidneys with a maximal GS% of 6% to 10%, 1377 recipients received kidneys with a maximal GS% of 11% to 20%, and 442 recipients received kidneys with a maximal GS% of >20%. Similarly, 11 660 recipients received kidneys with a minimal GS% of 0% to 5%, 2440 recipients received kidneys with a minimal GS% of 6% to 10%, 1365 recipients received kidneys with a minimal GS% of 11% to 20%, and 400 recipients received kidneys with a minimal GS% of >20% (Table 4).

Table 3
Demographic characteristics (graft and patient survival models of the program-specific reports).

Characteristic	Value (N = 30 985)
Recipient	
Age, mean ± SD (y)	52.0 ± 13.0
Male sex	59.5%
Race	
Asian	7.4%
Black	34.2%
Multiracial	0.7%
Native American	1.1%
Pacific Islander	0.5%
White	56.1%
Weight, mean ± SD, kg[a]	81.7 ±18.9
BMI, mean ± SD[b]	28.2 ± 5.3
Dialysis duration, mean ± SD (y)	6.3 ± 5.6
Cause of ESKD	
Diabetes mellitus	28.7%
Hypertension	26.2%
Glomerulonephritis	22.3%
Other	20.8%
Missing	0.3%
Donor	
Age, mean ± SD (y)	38.1 ± 15.4
KDRI score, mean ± SD[c]	1.24 ± 0.35
Diabetes mellitus	7%
Hypertension	28.2%
DCD	22.0%
Terminal creatinine, mean ± SD, mg/dL	1.24 ± 1.0
Donor organ source local (vs shared)	30.9%
CIT, mean ± SD (h)	17.9 ± 8.4
HLA mismatch, mean ± SD	4.1 ± 1.5

BMI, body mass index; CIT, cold ischemia time; DCD, donation after cardiac death; ESKD, end-stage kidney disease; HLA, human leukocyte antigen; KDRI, Kidney Donor Risk Index.
[a] 0.14% missing.
[b] 0.13% missing (BMI calculated as weight in kilograms divided by height in meters squared).
[c] 0.91% missing.

Association of glomerulosclerosis and kidney yield

Maximal GS% was plotted against kidney yield, stratified by the level of minimal GS%. Irrespective of the level of minimal GS%, the increasing level of maximal GS% was associated with lower yield. This effect was most pronounced when maximal GS% reached >20%. Similarly, regardless of the level of maximal GS%, increasing level of minimal GS% was associated with lower yield. This effect was most pronounced when the minimal GS% reached >20%. For example, when the maximal GS% was 0% to 5% (meaning, by definition, that minimal GS% could be no greater than 0% to 5%), kidney yield was ~1.63. In contrast, when maximal GS% was >20% and minimal GS% was also >20% (representing the worst-case scenario of GS%), kidney yield was only ~0.88. When the GS% was unavailable or unknown, generally a situation in which no biopsy was performed for purposes of clinical decision-making (with kidneys presumably being judged as either clearly acceptable or unacceptable), kidney yield was ~1.41 (Fig. 1).

Associations of glomerulosclerosis percentage with graft failure and patient mortality

The associations between the level of minimal GS% and the outcomes of graft failure and patient mortality at 1-year posttransplant are shown in Figure 2. For graft failure, when the minimal GS% reached 16% to 20%, the hazard ratio (HR) was 1.07, and when the minimal GS% was >20%, the HR reached 1.28. For patient mortality, when the minimal GS % reached >20%, the HR of 1-year mortality reached 1.19.

Impact of incorporating glomerulosclerosis percentage to the risk-adjusted kidney yield model of organ procurement organization–specific reports

Inclusion of minimal GS% to the yield model did not change the predictability of the model significantly, as can be observed by the data points consistently falling along the 45° line (Fig. 3). The HR was almost identical with or without the inclusion of minimal GS%.

Impact of incorporating glomerulosclerosis percentage on the risk-adjusted kidney graft and patient survival models of program-specific reports

All data points fell on the 45° lines, suggesting that inclusion of minimal GS% to the posttransplant survival models had minimal impact in predicting graft (Fig. 4A) or patient (Fig. 4B) survival. The HRs remained similar regardless of the inclusion of information on minimal GS%. Similarly, the inclusion of minimal GS% to the 3-year posttransplant survival models had minimal impact in predicting graft or patient survival (data not shown).

Discussion

The issue of whether and how to incorporate organ quality, for which GS% is a proxy, into SRTR's OSR yield and PSR outcome models has been a source of considerable debate. Partially in response to the

Table 4
Level of GS% in recipients with transplanted kidneys that were biopsied.[a]

Minimal GS%	Maximal GS%				
	NA/UNK	0% to 5%	6% to 10%	11% to 20%	>20%
NA/UNK	15 119 (48.79%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
0% to 5%		11 607 (37.46%)	31 (0.10%)	19 (0.06%)	3 (0.01%)
6% to 10%			2408 (7.77%)	26 (0.09%)	6 (0.02 %)
11% to 20%				1332 (4.30%)	33 (0.11 %)
>20%					400 (1.29 %)

GS, glomerulosclerosis; NA, not applicable; UNK, unknown.
[a] N = 30 984.

concerns of the transplant community, SRTR incorporated the level of GS% into its models in January 2020. To determine the potential impact of this policy change, we sought to determine the associations between kidney procurement biopsy findings and organ yield in the OSRs and the PSR outcome of all-cause kidney transplant graft failure and posttransplant mortality. We found, not unexpectedly, that increased level of GS% was associated with lower organ yield and inferior patient and graft survival after kidney transplant. However, the relationships among the projected and observed outcomes for organ yield, graft failure, and mortality—the relationships that may influence the decision to accept or turn down an organ for procurement—appear to be unaffected by the inclusion of GS%. The inclusion of GS% into the yield and PSR models should reassure OPOs and transplant programs that organs with high levels of GS% can be procured and transplanted, potentially contributing to maximal organ utilization.

Biopsies are commonly performed in the United States because of their perceived value in guiding clinical decision-making on both procurement[6] and implantation,[13] in part because OPOs do not benefit from procuring kidneys that are eventually judged to be unsuitable for transplant. Although biopsy criteria vary by OPOs, a procurement biopsy is often performed when there is concern about the quality of the kidneys based on the clinical parameters alone. For example, with the increase in the Kidney Donor Profile Index (which incorporates only clinical parameters), the biopsy rate increases in parallel.[14] Indeed, the mere decision to perform a procurement biopsy (irrespective of the biopsy findings themselves) was associated with a >3-fold likelihood of discard, even after adjustment for multiple donor factors.[14]

As might be expected, suboptimal findings on biopsy are one of the most important reasons for kidney discard.[15] For example, in a study of >23 000 kidneys of relatively low quality (Kidney Donor Profile Index > 85%), Cheungpasitporn et al[16] found that >90% of the recovered kidneys were biopsied and more than half of them were discarded. While this study did not appear to use multivariable adjustment, the rate of discard increased proportionally with the increasing GS%.[16] This finding is concordant with those of the present study, which, to our knowledge, is the first to quantify the association between GS% and yield. We found that when GS% exceeded 20% in both kidneys, the discard rate was nearly twice that when GS% was ≤5% in both kidneys. However, excessive discard of kidneys has potentially profound importance for the availability of kidneys in the United States: a recent study suggested that

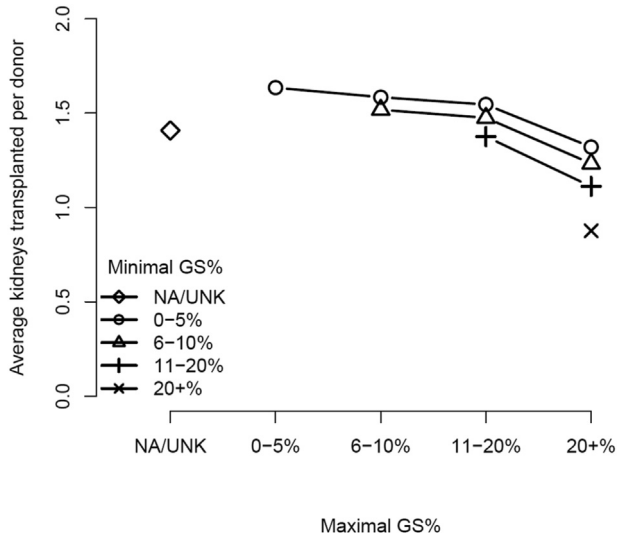

Figure 1. Level of GS% and kidney yield. GS, glomerulosclerosis; NA, not applicable; UNK, unknown.

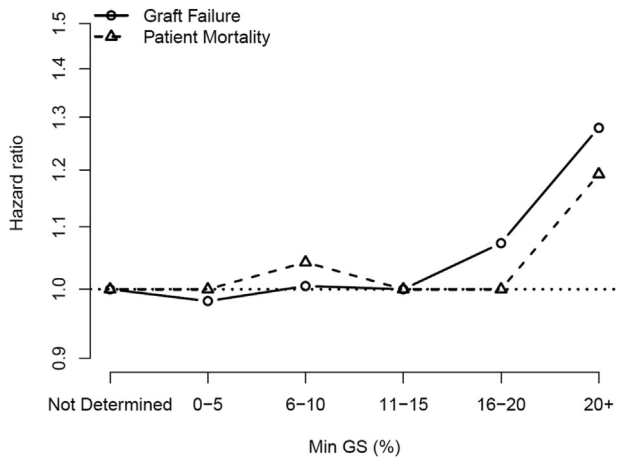

Figure 2. Association of level of GS% with and graft and patient outcomes (program-specific report model). GS, glomerulosclerosis; Min, minimal.

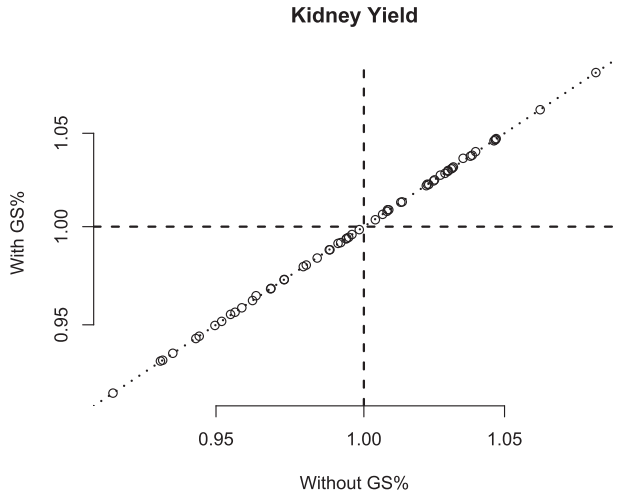

Figure 3. Impact of incorporation of minimal GS percentage on the risk-adjusted kidney yield model of the organ procurement organization–specific reports. The data shown are the observed/expected donor yield ratio and hence are close to 1.0. GS, glomerulosclerosis.

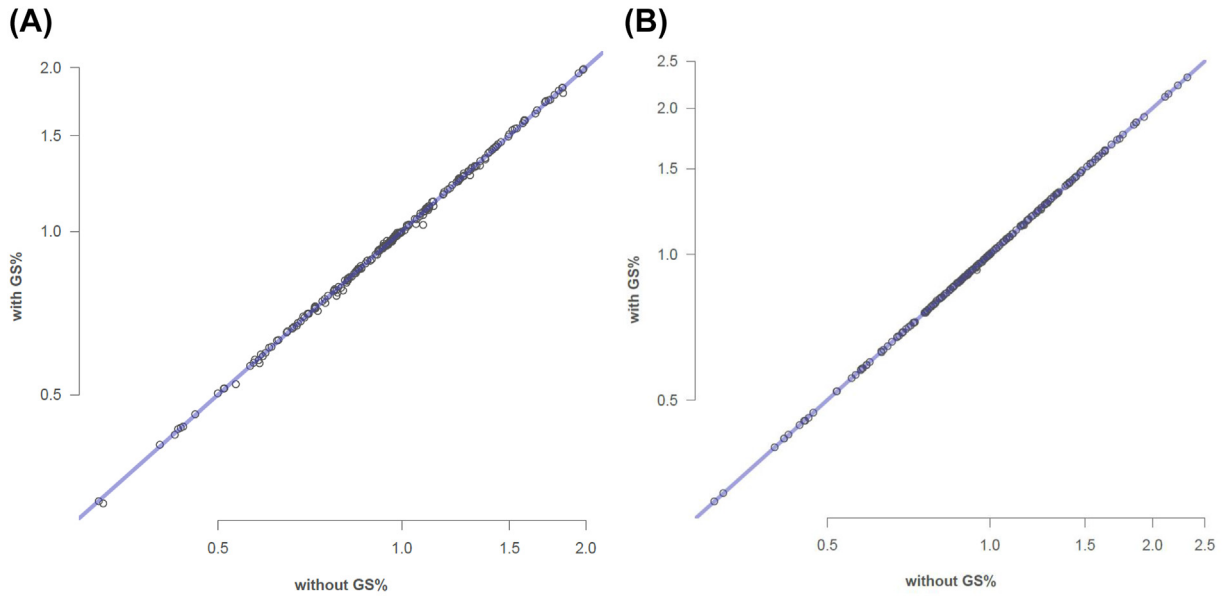

Figure 4. (A) Impact of incorporation of the minimal GS% on the risk-adjusted kidney model predicting 1-year graft survival of program-specific reports. The x-axis shows the original model without inclusion of the minimal GS%, and the y-axis shows the model that includes it. The data shown are the observed/expected hazard ratios on the log scale. (B) Impact of incorporation of minimal GS% on the risk-adjusted kidney model predicting 1-year patient survival of program-specific reports. The x-axis shows the original model without inclusion of the minimal GS%, and the y-axis shows the model that includes it. The data shown are the observed/expected hazard ratios on the log scale. GS, glomerulosclerosis.

fully 60% of the kidneys discarded in the United States would have been suitable for transplant in Europe.[17] In Europe, kidney biopsies prior to procurement are rarely performed.

In addition to having implications for OPOs, procurement biopsies have implications for transplant programs, which have concerns that poor biopsy findings might result in unfavorable graft and patient survival—with ensuing adverse impact on the transplant center's performance evaluation. Evidence of an association between GS% and posttransplant outcomes, however, is mixed, perhaps because procurement biopsy is an imprecise way to evaluate kidney quality, at least compared with implantation biopsy.[18] Factors such as inadequate sampling, poor handling of tissue, and lack of expertise in interpretation (when performed by an "on-call" pathologist, as opposed to a dedicated kidney pathologist) are all potential reasons for discordant findings regarding the ability of procurement biopsies to predict posttransplant outcomes.[15] Perhaps surprisingly, in a study of nearly 6000 extended-criteria donor kidneys, Sung et al[5] found that the degree of GS % was not associated with graft survival. Similarly, Edwards et al,[19] in a study of nearly 3500 kidneys, found that GS% of >20% was not associated with graft failure. In distinction, 2 studies collectively encompassing more than 18 000 kidney transplant recipients demonstrated an association between GS% and graft failure.[4,20] However, both of these studies used very low thresholds to determine the presence of GS at 5%[4] and 10%.[20] The findings of the present study, seemingly the largest and most contemporary to date, encompassing all procurement biopsies performed in the United States between mid-2017 and mid-2019, suggest that a cutoff of ≥16% is associated with graft failure. This level of GS% was also associated with mortality, an outcome which other studies have not investigated.

Another limitation of the use of an "on-call pathologist" is that other biopsy features besides GS% are less likely to be reported. Thus, decisions on whether to use the kidney are typically made on the basis of GS% alone. Therefore, it is not possible to study the association of other biopsy features with the kidney yield or the posttransplant outcomes.

Our study cannot be used to definitively answer the question of whether and how GS%, as determined by procurement biopsy, is associated with outcomes. Only a clinical trial, in which all but the poorest kidneys were spared discard and implanted in suitable candidates, could measure the true relationship. However, a strength of our study is its use of the entire population of all kidneys transplanted in the United States during the period studied.

In summary, our study suggests that poor kidney biopsy findings, as quantified by the level of GS% at the time of procurement, are associated with lower organ yield attributable to higher rates of discard by OPOs. A GS level of ≥16% is associated with lower organ and patient survival. Incorporation of GS% into the traditional yield and PSR models did not alter their ability to predict outcomes, perhaps because the legacy models perform very well in predicting outcomes. However, incorporation of GS% into the yield and PSR models may serve to reassure OPOs (for whom yield is important) as well as clinicians and transplant centers (for whom outcomes, as evaluated by the PSR models, are of paramount importance) that they will not be unfavorably evaluated should they decide to pursue transplant utilizing kidneys with relatively high levels of GS%. This reassurance could promote the use of organs with higher levels of GS% and reduce discard rates—a desirable outcome because even suboptimal kidneys confer a survival advantage compared with remaining on dialysis, at least in appropriately selected transplant candidates.

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Disclosure

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Data availability

The data that support the findings of this study are available from the Scientific Registry of Transplant Recipients.

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