ORIGINAL ARTICLE

Predicting skin cancer in organ transplant recipients: development of the SUNTRAC screening tool using data from a multicenter cohort study

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SUMMARY

Skin cancer is a common post-transplant complication. In this study, the Skin and Ultraviolet Neoplasia Transplant Risk Assessment Calculator (SUNTRAC) was developed to stratify patients into risk groups for post-transplant skin cancer. Data for this study were obtained from the Transplant Skin Cancer Network (TSCN), which conducted a multicenter study across 26 transplant centers in the United States. In total, 6340 patients, transplanted from 2003 and 2008, were included. Weighted point values were assigned for each risk factor based on beta coefficients from multivariable modeling: white race (9 points), pretransplant history of skin cancer (6 points), age ≥ 50 years (4 points), male sex (2 points), and thoracic transplant (1 point). Good prognostic discrimination (optimism-corrected c statistic of 0.74) occurred with a 4-tier system: 0–6 points indicating low risk, 7–13 points indicating medium risk, 14–17 points indicating high risk, and 18–22 points indicating very high risk. The 5-year cumulative incidence of development of skin cancer was 1.01%, 6.15%, 15.14%, and 44.75%, for Low, Medium, High, and Very High SUNTRAC categories, respectively. Based on the skin cancer risk in different groups, the authors propose skin cancer screening guidelines based on this risk model.

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Introduction

There has been a 20% increase in solid organ transplantation in the past 5 years; over 33 600 procedures were performed in 2016 worldwide [1,2]. Fortunately, with the development of novel immunosuppressant medications, solid organ transplant recipients (SOTR) are now living longer, healthier lives [2]. With fewer deaths attributable to organ rejection, these individuals are now living long enough to develop delayed health complications such as malignancy. It is well known that SOTR are at an increased risk of developing skin cancer compared with the nontransplant population. The increased risk is most likely due to the immunosuppressive medications that these patients take to prevent organ rejection [3,4]. Studies report a risk for cutaneous squamous cell carcinoma (cSCC) approximately 40–250 times higher than that in the general background population, and a threefold increase in risk for malignant melanoma (MM) [5–10]. Overall, approximately 14% of all SOTR will develop skin cancer within 10 years of solid organ transplantation [11].

Multiple studies have identified individual SOTR characteristics that increase chances of skin cancer after organ transplantation. Predictors of post-transplant skin cancer include male sex, white race, older age at transplantation, fair skin and light eyes, tendency to sunburn versus suntan, and heart/lung versus kidney/liver transplant [3–6,12,13]. Although predictors have been well characterized, few risk stratification tools have been developed to guide physicians in determining skin cancer screening intervals [14]. The inability to accurately stratify SOTR risk of skin cancer formation has prevented the development of high-quality, evidence-based screening recommendations.

A Delphi panel consensus survey conducted by Crow *et al.* [15]. utilized a panel comprised of both transplant physicians and dermatologists to develop consensus guidelines for post-transplant skin cancer screening. Panelists from this survey emphasized a need for a simple, effective tool to risk stratify patients for skin cancer screening. While most clinicians agree transplant patients need to be screened, there is a lack of consensus on when these patients should be screened. In this study, we sought to develop a prediction tool to risk stratify patients regarding the development of the first skin cancer post-transplantation. This tool can be utilized by transplant care providers to determine when to refer patients for skin cancer screening, and ultimately aims to reduce morbidity from keratinocyte carcinoma.

Materials and methods

Study design and acquisition of data

This algorithm was designed based on a recent Delphi-method expert consensus panel that agreed upon the need for a simple risk prediction calculator for skin cancer after transplant. The data for this study were considered in conjunction with the recommendations of the panel, which utilized an 80% *a priori* consensus to determine that skin cancer screening is warranted if the risk of skin cancer in a population is at least 2% [15]. Therefore, experts felt that screening a group of 100 patients would be worthwhile in order to detect two patients with skin cancer.

The data for this study were obtained from the Transplant Skin Cancer Network (TSCN) study, a multicenter study across 26 transplant centers in the United States [11]. Participation in the TSCN study was open to any US transplant center. Adult (≥18 years) recipients of a first solid organ transplant (lung, heart, kidney, pancreas, or liver) performed from January 1, 2003, through December 31, 2003, or between January 1, 2008, through December 31, 2008, were eligible for inclusion. These two specific calendar years were selected to allow at least 5 and 10 years of follow-up based on when the parent study was performed (2013), and to capture era effect changes in immunosuppression regimens. Intestinal transplant patients were excluded due to the small number of patients in that cohort.

Eligible subjects were identified using the Organ Procurement Transplant Network/United Network for Organ Sharing (OPTN/UNOS) Standard Transplant Analysis and Research (STAR) file, which contains pre- and post-transplant data on every transplant occurring in the United States. The study end date was December 31, 2013. Patients who were retransplanted during the follow-up period were included in the study, but had their follow-up time collapsed into one period. Patient-specific dermatology information, including follow-up time period and outcome, was obtained from review of each subject's medical record. Since measuring the type and duration of immunosuppression is a difficult variable to measure, the type of organ transplanted was utilized as a proxy level of immunosuppression. The primary outcome of the parent study was time to development of the first invasive cSCC, MM, or Merkel cell carcinoma (MCC). Basal cell carcinoma (BCC) was not captured due to the limited morbidity and mortality from this cancer compared to cSCC, MM, or MCC in transplant recipients. All data were stored in a RedCap

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database. Further details on the methodology of this study are available for review in the parent manuscript [11]. This study was approved by the University of California San Francisco Institutional Review Board.

Statistical analysis

Predictor variables obtained from the STAR file included sex, race, age, and type of organ transplanted. Skin cancer history and outcomes were obtained from comprehensive medical record review. Year of transplant and residential zip code at the time of transplantation were included in the parent study but were not incorporated into the screening tool, as the former is not relevant to prospective skin cancer screening and the latter was not a significant predictor of skin cancer risk.

To account for the competing risk of nonskin cancer-related death, a multivariable Fine and Gray [16] subdistribution hazards model was utilized to estimate the independent association between risk factors and skin cancer development during the post-transplant period. Our model covariates were specified *a priori* based on the previously reported adjusted multivariable model (details on model development can be obtained from the parent manuscript [11]). The adjusted risk factors associated with skin cancer development included age $\geq$ 50 years, male sex, thoracic organ transplant (heart or lung), pre-transplant history of skin cancer, and white versus non-white race. Integer point scores for each individual factor were generated by dividing the beta coefficient for a risk factor by the smallest beta coefficient, and then rounding to the nearest whole number. This point value reflected the relative contribution of that risk factor to the overall model. The point values were tabulated and summed for each patient (0–22 points), and the incidence of skin cancer and 95% CI were calculated for each point category (Table S1). This 22-level score was collapsed into a four-level variable with recursive partitioning using classification and regression tree analysis: low risk, medium risk, high risk, and very high risk. A four-tiered system was ultimately chosen by naturally collapsing groups that had similar incidence of skin cancer formation to allow for ease of use in risk prediction. The splits obtained were compared to the cumulative incidence functions and cumulative incidence at 1, 2, and 5 years for verification.

Cumulative incidence function curves were generated to demonstrate the incidence of skin cancer over time in the four Skin and Ultraviolet Neoplasia Transplant Risk Assessment Calculator (SUNTRAC) risk groups. The discrimination of the hazard model was assessed using Wolber's concordance index for survival models with competing risks [17]. We assessed the optimism of the model with 100 cycles of bootstrap with replacement [18,19]. All analysis was done using STATA Corp v 14.0 (College Station, TX, USA).

Results

The final TSCN study cohort consisted of 10 648 transplant recipients. Of these, 4308 patients were excluded because outcome or risk factor data were missing. In the parent study, multiple sensitivity analyses accounting for missing data were performed and the final model did not change significantly. The SUNTRAC model and tool were developed based on the 6340 patients with complete risk factor and outcome data. Table 1 lists baseline demographics of the study cohort. The median age at transplantation was 53 (interquartile range 44–61). The majority of transplant patients were male (n = 4050; 63.88%) and white (n = 4402; 69.43%). Approximately half of all organs transplanted were kidney transplants (n = 3316; 52.30%).

Eight hundred and sixty-five patients (13.64%) developed skin cancer, including cSCC, MM, or MCC, during the post-transplant period. The risk factors on multivariable Cox analysis associated with skin cancer formation were white race (subdistribution hazards ratio (SHR) 8.78; 95% CI 6.05–12.76; point value = 9), pretransplant history of skin cancer (SHR 4.59; 95% CI 3.34–6.10; point value = 6), age $\geq$ 50 years (SHR 2.46; 95% CI 2.03–2.98; point value = 4), male sex (SHR 1.53; 95% CI 1.29–1.82; point value = 2), and thoracic organ (heart or lung) transplant (SHR 1.28; 95% CI 1.08–1.53; point value = 1). (Table 2) The final SUNTRAC tool was divided into four categories: low risk: 0–6 points, medium risk: 7–13 points, high risk: 14–17 points, and very high risk: 18–22 points. In total, 1870 (29.49%) patients were in the Low-Risk group, 2379 (37.52%) were in the Medium-Risk group, 1989 (31.37%) were in the High-Risk group, and 102 (1.60%) were in the Very High-Risk group. The crude proportion of patients developing skin cancer (cSCC, MM, or MCC) during the post-transplant period in the Low-Risk, Medium-Risk, High-Risk, and Very High-Risk groups was 1.66% (95% CI 1.17–2.35), 10.80% (95% CI 9.62–12.12), 25.64% (95% CI 23.77–27.61), and 65.69% (95% CI 55.93–74.27), respectively (Table 3).

The median follow-up time was 6.1 years (interquartile range 3.1–7.5 years). The cumulative incidence function curves for the SUNTRAC categories demonstrated a clear separation in failure rates between the

Table 1. Baseline demographics of the study cohort (n = 6340).

Characteristics	Number (%)
Age at diagnosis, median [IQR], year	53 [44–61]
Sex	
Male	4050 (63.9)
Female	2290 (36.1)
Race (categorical)	
White	4402 (69.4)
Black	847 (13.4)
Hispanic	649 (10.2)
Asian	325 (5.1)
Other*	117 (1.85)
Race (dichotomized)	
White	4402 (69.4)
Nonwhite	1938 (30.6)
Organ (categorical)†	
Lung‡	545 (8.6)
Heart	495 (7.8)
Kidney	3316 (52.3)
Pancreas§	246 (3.9)
Liver	1735 (27.4)
Organ (dichotomized)	
Thoracic	1040 (16.4)
Abdominal	5297 (83.6)

IQR, Interquartile range.
*Includes American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, multiracial, and unknown.
†3 patients had missing transplanted organ information.
‡Includes kidney–pancreas transplants.
§Includes heart–lung transplants.

risk groups (Fig. 1). Table 4 reports the cumulative incidence of skin cancer based on SUNTRAC risk category. There was an increased incidence of skin cancer at any given time point between the SUNTRAC groups. The 5-year and 10-year cumulative incidence of first skin cancer was 1.01% and 2.33% for low risk, 6.15% and 13.73% for medium risk, 15.14% and 31.75% for high risk, and 44.75% and 74.85% for very high risk, respectively. Our model accurately predicted skin cancer, with an adapted c statistic of 0.75 and an optimism-corrected c statistic of 0.74.

Discussion

With the survival of transplant patients increasing, the risk of long-term complications, including skin cancer, increases. In a recent U.S. study, 14% of all SOTR developed skin cancer within 10 years of transplantation [11]. Since the majority of transplant patients never develop skin cancer [11], but adherence to annual screening is associated with reduction in skin cancer morbidity [20], it is important to determine who should be referred for skin cancer screening and when. Inappropriate referrals for skin cancer screening lead to overutilization of healthcare resources for low risk patients while preventing high risk patients from being screened in a timely fashion. We propose the Skin and Ultraviolet Neoplasia Transplant Risk Assessment Calculator (SUNTRAC): a skin cancer risk prediction tool that transplant providers can use to determine whether and when patients need to be referred to dermatology for skin cancer screening. The goal of this tool is to prioritize post-transplant referrals for skin cancer screening and ultimately allow for early detection and decreased morbidity from skin cancer.

The SUNTRAC tool is built from five risk factors associated with skin cancer development on multivariable modeling: white race, pretransplant history of skin cancer, age ≥ 50 years at the time of transplant, male sex, and history of heart or lung transplant. These factors have been consistently reported in other studies to be associated with skin cancer development in this population. Good prognostic stratification occurred with the 4-tiered system outlined in Table 3.

There were very few cases of skin cancer in the SUNTRAC Low-Risk group, with only 1.7% of patients developing skin cancer during the post-transplant period. The highest risk for skin cancer occurred in the Very High-Risk group, with nearly two-thirds of patients developing a skin cancer during the post-transplant period. In order to be considered a very high risk patient, the transplant recipient must be Caucasian or have a pretransplant history of skin cancer, and possess one of the following additional risk factors: age ≥50 years old at the time of transplant, male sex, or be a heart or lung transplant recipient. In the Very High-risk group, 8.9% of patients developed skin cancer by one year post-transplant, and 44.7% of patients developed skin cancer by 5 years post-transplant. Table 5 outlines the screening recommendations based on the recommended 2% incidence threshold as a minimum of when patients should be screened after transplant.

When applied to the TSCN data, routine skin cancer screening by a dermatologist performing full body skin examination should be done within 10 years, 2 years, 1 year, and 6 months post-transplant for low risk, medium risk, high risk, and very high risk patients, respectively. A clinical algorithm incorporating the SUNTRAC weighted skin cancer risk factors (Fig. 2) facilitates risk stratification into one of the four risk categories. At the

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Table 2. Subdistribution hazard ratios (SHR) based on TSCN study [11] and point value assignment for each risk category in the Skin and Ultraviolet Neoplasia Risk Assessment Calculator (SUNTRAC).

Variables	n (%)	Subdistribution hazard ratio (95% CI)	Beta coefficient (95% CI)	Point value
White race	4402 (69.4)	8.78 (6.05–12.76)	2.17 (1.80–2.55)	9
Pretransplant history of skin cancer		4.59 (3.45–6.1)	1.52 (1.24–1.81)	6
Age ≥ 50		2.46 (2.03–2.98)	0.90 (0.71–1.09)	4
Male	4050 (63.9)	1.53 (1.29–1.82)	0.43 (0.26–0.60)	2
Heart or Lung transplant	1040 (16.4)	1.28 (1.08–1.53)	0.25 (0.08–0.43)	1

CI, confidence Interval; TSCN, Transplant Skin Cancer Network; SUNTRAC, Skin and Ultraviolet Neoplasia Transplant Risk Assessment Calculator.

Table 3. Proportion of patients with skin cancer stratified by SUNTRAC category.

Risk category (points)	All patients (*N*)	Patients without cancer: N (%; 95% CI)	Patients with skin cancer: N (%; 95% CI)
1: low risk (0–6)	1870	1839 (98.34; 97.65–98.83)	31 (1.66; 1.17–2.35)
2: medium risk (7–13)	2379	2122 (89.20; 87.88–90.38)	257 (10.8; 9.62–12.12)
3: high risk (14–17)	1989	1479 (74.36; 72.39–76.23)	510 (25.64; 23.77–27.61)
4: very high risk (18–22)	102	35 (34.31; 25.73–44.07)	67 (65.69; 55.93–74.27)
Total	6340	5475 (86.36; 85.49–87.18)	865 (13.64; 12.82–14.51)

CI, confidence interval; ITSCC, International Transplant Skin Cancer Collaborative; SUNTRAC, Skin and Ultraviolet Neoplasia Risk Assessment Calculator.

time of this publication, a smartphone application is available for use in the clinical setting (Fig. 3). Regardless of SUNTRAC risk category, if the patient has a concerning lesion on the skin or other skin concern, they should be referred to dermatology promptly for evaluation. As noted by the Delphi expert panel consensus, patients with a pretransplant history of skin cancer should continue regular follow-up as determined by his or her dermatologist, regardless of SUNTRAC risk score.

The advantage of this system is that it is simple to calculate and does not require specific expertise or patient-reported variables. Panelists in the Delphi study agreed that a feasible risk assessment tool would take <5 min to perform and be performed by office staff. While a more detailed model may improve goodness of fit, it likely would be too laborious for a busy transplant team to use. Prior prediction tools incorporating patient-reported sun exposure history have not been widely adopted for this reason [14]. In addition, while further discrimination between intermediate risk groups might improve model fit, the additional data would not translate into a significant clinical difference in

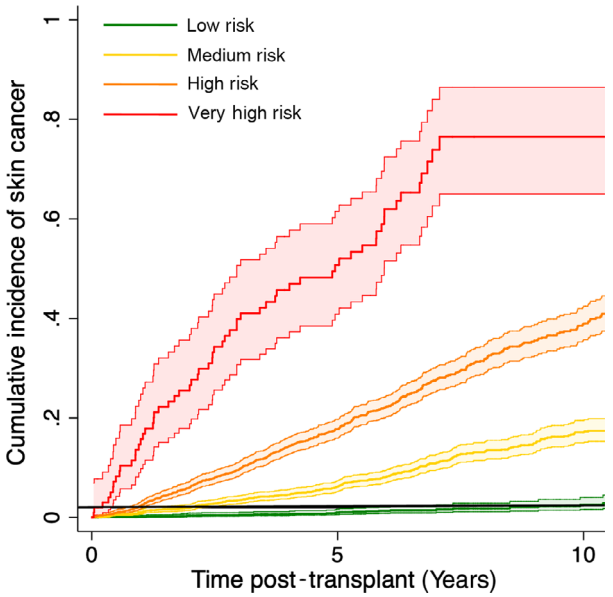

Figure 1 Cumulative incidence function curves for the Skin and Ultraviolet Neoplasia Transplant Risk Assessment Calculator (SUNTRAC) Tool. The faded orange-, green-, red-, and blue-shaded areas represent the 95% confidence interval for low risk, medium risk, high risk, and very high risk, respectively. Horizontal black line indicates screening threshold of 2%.

Table 4. Cumulative incidence of skin cancer over time for each SUNTRAC risk category.

Time in years	low risk (%)	medium risk (%)	high risk (%)	very high risk (%)
1	0.16	1.00	2.56	8.94
2	0.36	2.21	5.61	18.83
3	0.58	3.55	8.94	28.70
4	0.80	4.88	12.14	37.35
5	1.01	6.15	15.14	44.75
10	2.33	13.73	31.75	74.85

SUNTRAC, Skin and Ultraviolet Neoplasia Risk Assessment Calculator.

recommendation of screening within 1 year (high risk) and 2 years (medium risk). Additional data may improve predictions for low risk patients.

There are four published evidence-based risk stratification tools developed to date to determine the chances of developing keratinocyte carcinoma in the SOTR population [21–24]. Three of these studies included renal transplant recipients only, with cohort sizes ranging from 100 to 400 white renal transplant recipients. All tumors were histologically confirmed, and the models were validated via split cohort or jackknife methods. Some of the risk predictors included were male sex, older age at transplant, pre-existing cSCC, years living in a hot country, Fitzpatrick skin type I, and a history of childhood sunburn. None of the studies included dose or specified immunosuppression. The last study was limited to liver transplant recipients and identified white race, age ≥ 47, male sex, BMI ≤ 40, and lack of sirolimus use as risk factors for keratinocyte carcinoma post-transplantation [24]. Limitations of that study were that the skin cancer information was obtained from OPTN/UNOS, which has been previously demonstrated to poorly capture keratinocyte carcinoma cases [25].

In contrast, the SUNTRAC tool is based off a larger, racially diverse US population-based cohort of transplant patients across all organ types and accounts for duration of immunosuppression, and does not require a patient survey to determine sun exposure or sun sensitivity. While it is important for all SOTR to receive information regarding skin cancer risk, sun protection education, and to be questioned by transplant providers regarding new or concerning skin lesions, the threshold for dermatology referral for skin cancer screening should be tailored to the patient population and resources available within the healthcare system. The SUNTRAC tool was built from risk factors identified from a large, representative heterogeneous population of US-based transplant recipients, and aims to optimize screening in a resource-limited healthcare system. Another strength of this screening tool is the inclusion of patients transplanted as late as 2003 and 2008, allowing for satisfactory follow-up time, but avoiding a possible bias from the declining risk of post-transplant skin cancer since the mid-1980s [26,27].

In a recent systematic review of cancer screening clinical practice guidelines (CPGs) after transplantation, 10 manuscripts were identified and nine recommended a skin cancer screening examination on an annual basis [28]. All recommendations were limited to expert opinion rather than formal consensus or evidence-based guideline. The SUNTRAC tool discussed in this paper and the accompanying Delphi consensus recommendation for screening provide a refined recommendation for skin cancer screening after transplant.

Table 5. Post-transplantation initial screening guidelines based on SUNTRAC and Expert Consensus Panel Guidelines [15].

Risk category	Initial screening guidelines for referral to dermatology
low risk	• Problem/lesion focused (patient or provider initiated) at any time in the post-transplant period • Routine post-transplant skin cancer screening by 10 years
medium risk	• Problem/lesion focused (patient or provider initiated) at any time in the post-transplant period • First post-transplant skin cancer screening by 2 years
high risk	• Problem/lesion focused (patient or provider initiated) at any time in the post-transplant period • First post-transplant skin cancer screening by 1 year
very high risk	• Pretransplant skin cancer screening • Problem/lesion focused (patient or provider initiated) at any time in the post-transplant period • First post-transplant skin cancer screening by 6 months

Referral to a specialized transplant dermatologist where available.

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Figure 2 Decision tree representation of the decision logic utilized to create four Skin and Ultraviolet Neoplasia Transplant Risk Assessment Calculator (SUNTRAC) categories.

Figure 3 The Skin and Ultraviolet Neoplasia Transplant Risk Assessment Calculator (SUNTRAC) smartphone application can be downloaded and used in the clinical setting to risk stratify patients (currently available in iOS, in development for Android OS).

There are several limitations to this study. Limitations to the TSCN cohort dataset include the retrospective nature of the data, missing data, and bias toward academic medical center participation, as previously described. There are factors predictive of skin cancer development that are not included in our system,

including Fitzpatrick skin type, ultraviolet exposure, and immunosuppressive medication. Fitzpatrick skin type may be a better measure of risk than race, but this variable is not routinely captured in electronic health records. Race, which is correlated with skin type, is a reasonable and practical proxy for risk assessment. In addition, given the low number of skin cancers in non-white patients in the TSCN database, these categories had to be collapsed for statistical power. Since the SUNTRAC tool is meant to be used at the time of transplant, the baseline risk assessment cannot include post-transplant risk factors such as the level, duration, and type of immunosuppression. Future studies, ideally performed prospectively with patient-reported variables, may refine this system. Finally, this system needs to be externally validated in an independent dataset.

The SUNTRAC tool is limited to use in prediction of the UV-associated neoplasias cSCC, MM, and MCC. Its use cannot be extrapolated to other cutaneous malignancies such as Kaposi's sarcoma, or to genital SCC. In addition, SUNTRAC does not inform the frequency of repeat follow-up screening intervals, which remains an important topic within the field of transplant skin cancer. There is no evidence-based consensus on screening intervals, though expert opinion suggests that low risk patients with no history of skin cancer may be followed annually by the transplant team until lesions arise [29].

The SUNTRAC tool is an easy-to-use tool to help transplant providers' risk assess patients and guide dermatology referral for skin cancer screening by full body skin examination. Accurate risk prediction for skin cancer development is important for the transplant community in order to ensure high-quality and timely care for patients, while optimizing utilization of limited healthcare resources. In addition, it helps to identify a high risk subset that may benefit from pre- and post-transplant education, preventive strategies such as aggressive treatment of field cancerization, and inclusion criteria for clinical trials aimed to decrease the morbidity and mortality of post-transplant skin cancer. Further studies are required to validate and refine this system and to evaluate its impact on clinical practice and patient outcomes.

Authorship

AJP, STA, and GLG: designed the study, collected study data, analyzed study data, and wrote the paper. LDC, SL, MLM, AC, and JB: analyzed data, created figures and tables, and assisted in the development of the manuscript.

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Conflict of interest

The authors have declared no conflicts of interest.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. Total point value for each patient in study cohort (N = 6340).

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