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ORIGINAL ARTICLE

Seasonal trends in donor heart availability: an analysis of the UNOS database

Mohammed A. Kamalia[1], Nathan J. Smith[2], Lisa Rein[3], Adhitya Ramamurthi[4], Bryan Miles[1], Lyle D. Joyce[2], Asim Mohammed[5] & David L. Joyce[2]

1 Medical College of Wisconsin, Milwaukee, WI, USA
2 Department of Surgery, Division of Cardiothoracic Surgery, Medical College of Wisconsin, Milwaukee, WI, USA
3 Department of Biostatistics, Medical College of Wisconsin, Milwaukee, WI, USA
4 Department of Surgery, Medical College of Wisconsin, Milwaukee, WI, USA
5 Department of Internal Medicine, Division of Cardiology, Lutheran Health Physicians, Fort Wayne, IN, USA

Correspondence
Nathan J. Smith, MD, Department of Surgery, Division of Cardiothoracic Surgery, Medical College of Wisconsin, 8701 Watertown Plank Rd., Milwaukee, WI 53226, USA.
Tel./fax: (414) 955-6978;
e-mail: njsmith@mcw.edu

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SUMMARY

Despite the widespread belief that donor organ availability varies around holidays and seasons, there is little empirical data supporting this long-held belief. Variations in donor heart availability may be of interest to patients and clinicians. The UNOS/OPTN registry was queried for all heart donations from October 1987 through March 2017. Daily heart donation rates were modeled nationally using Poisson regression including splines for year and day of the year. Seasonality was assessed using a likelihood ratio test for the spine terms for day of the year. The holiday effect was assessed using conditional logistic regression. Seasonal plots suggest a significant, although modest, increase in organ availability during the summer months, except for region 1. The regions with the highest amplitude were region 7 (peak: June 21, amplitude: 16.63%) and region 6 (peak: July 5, amplitude: 11.29%). There was no significant difference in the odds of heart donation when comparing holidays vs. non-holidays using national data (odds ratio [95% CI]: 1.01 [0.98, 1.03], $P = 0.560$) or any regional subsets. There was no observable correlation between donor heart availability and holidays. However, a significant seasonality effect was observed with higher donation rates occurring during warmer months.

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Introduction

The disparity between the number of patients awaiting heart transplantation and the number of available donors continues to persist. Between 2009 and 2018, the number of patients listed for transplant increased dramatically (33.7%) from 2810 to 3756 [1]. While the number of available donors increased over the same interval (2281 to 3466), there remains a large discrepancy, leaving hundreds of patients still awaiting transplantation [1,2]. One contributing factor to this imbalance is the introduction of continuous flow left ventricular assist devices (LVADs) as a bridge-to-transplantation strategy, which in 2018 comprised 46.2% of patients receiving transplants [2]. As the incidence of device-related complications has decreased, these devices have contributed to improved waiting list survival [3]. It has long been believed, primarily based on anecdotal accounts and commonly shared beliefs, that warmer temperatures and holidays are associated

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with an increased availability of donor organs, higher donation rates, and, therefore, a higher probability of successful transplantation. To date, there is little empiric evidence to support or refute this theory. As the number of patients waiting for a heart transplant grows, knowledge of seasonal or holiday variability in donation patterns may be useful to transplant centers anticipating suitable organs for their listed patients, for example, by optimizing listed patients in the event of an organ offer or implementing stable LVAD patients' special 30-day enhanced status time (EST) to take advantage of an elevated priority status. Our goal was to identify any seasonal trends in heart transplant variability to lend objective evidence to confirm or refute these commonly held beliefs regarding organ availability and perhaps identify meaningful patterns of increased or decreased availability for use in the strategic listing of heart transplant patients as an adjunct to donor and recipient organ characteristics.

Methods

Annual, monthly, and daily heart donation rates were calculated from October 1987 through March 2017 on the national level and separately for each United Network for Organ Sharing (UNOS) region from the UNOS UNet database. Monthly rates were normalized to a 30-day period to account for differences in days of the month. No exclusion criteria were used for this study. Region reflects the UNOS region in which the organ was recovered. Dates reflect the date the donor entered the operating room for organ procurement. Rates include all hearts that were accepted by a transplant center and procured for donation (<2% were not transplanted).

Seasonal analysis

Daily heart donation rates were modeled using Poisson regression including splines for year and day of the year. A natural cubic spline with 3 degrees of freedom was used for year, and a periodic b-spline with 4 knots per year was used for day of the year. This analysis was repeated for the national data and separately for each UNOS region (see Figure S1). Seasonality was assessed using a likelihood ratio test for the spline terms for day of the year (Table S1). The estimated amplitude and date of seasonal peak were reported for the national and regional models (Figure S3). The amplitude was defined as the average of the absolute percent change between mean and maximum rates and mean and minimum rates.

Goodness of fit was visualized graphically by overlaying the estimated seasonal curve over the average monthly rates. The average monthly rates were estimated using a Poisson model fit to monthly data, including a cubic spline for year, month (categorical), and an offset term for days in each month. The marginal means and 95% confidence intervals were plotted as dots and whiskers. The fitted values from the seasonality model (fit to daily data) were overlaid as a smooth curve.

Holiday analysis

The daily number of recovered hearts was compared between holidays and regular days using a case-crossover model [4]. This model uses conditional logistic regression to compare cases (holidays) and neighboring controls (regular days) in blocks of 30 consecutive days. This stratification matches each holiday with nearby days within a limited window to control for any potential seasonal trends or trends across years. Holidays were defined as any day within the 7-day period surrounding any major U.S. holiday (New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, and Christmas Day). A 7-day period was chosen as a reasonable window given the intuitiveness of the time interval as it relates to calendar organization, but also as it was felt to be wide enough to encompass organ donations as a result of holiday-related activities preceding holidays and organ donations succeeding holidays, but nonetheless a result of holiday-related activities. A sensitivity analysis was performed for windows ranging from 3 to 7 days surrounding each holiday with similar results (Table S2 and Table S3).

All statistical analyses were performed using R version 3.6.0 (2019-04-26) (R Foundation for Statistical Computing, http://www.R-project.org). All p-values were 2-sided, and $p < 0.05$ was considered statistically significant. No corrections were made for multiple testing.

Results

Annual heart donation rates increased in a non-linear pattern over the study period, even after adjusting for population growth. A heat map for all UNOS regions was generated showing hearts recovered per month (Fig. 1). No obvious temporal trends in heart donation rates were appreciated, although organ recovery rates varied considerably between regions. A quantitative analysis of this same data revealed significantly higher rates of organ recovery during the summer months,

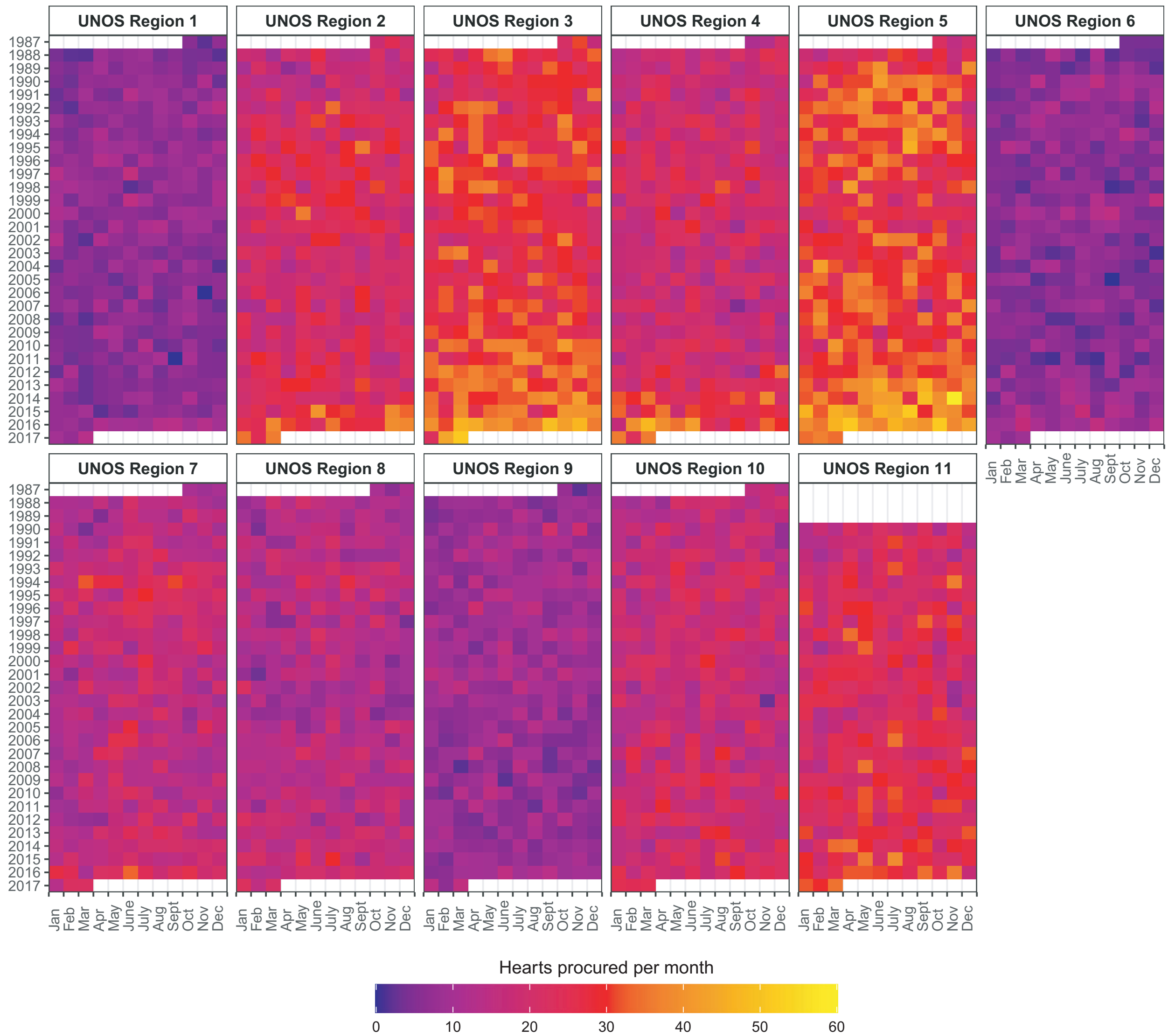

Figure 1 Region reflects the UNOS region in which the organ was recovered. Dates reflect the date the donor entered the operating room for organ recovery. A heat map was created where darker colors represent a lower number of hearts recovered per month and lighter colors represent a greater number of hearts recovered per month. No immediate temporal trends were observed; however, a pattern in different seasons is visible but difficult to see.

with a most pronounced effect in the northernmost regions (Regions 6 [11.29%] and 7 [16.63%]) (see Figure S3f,g). For reference, all UNOS regions are geographically represented with the lighter colored regions revealing a larger seasonality effect (Fig. 2). Seasonal plots suggest a modest increase in monthly donations in the summer months (see Figure S2 and Figure S3). A statistically significant seasonal pattern ($P < 0.001$) was detected in the national data (Fig. 3a) when looking at average number of hearts recovered per month with a peak amplitude of 7.84% being on June 3.

All regions except for UNOS region 1, which corresponds to the northernmost regions in the country, showed a statistically significant seasonal effect in heart donation rates (Table S1, Figure S3). Monthly heart recovery rates for UNOS Region 1 (Fig. 3c) revealed a flatter line and no statistically significant seasonal trend (Table S1, Figure S3a). The regions with the highest amplitudes were Region 7 (Illinois, Minnesota, North Dakota, South Dakota and Wisconsin; peak: June 21, amplitude: 16.63%, Fig. 3b, Figure S3g), region 6 (Alaska, Hawaii, Idaho, Montana, Oregon and Washington; peak: July 5, amplitude: 11.29%) (Figure S3f), and region 8 (Colorado, Iowa, Kansas, Missouri, Nebraska, and Wyoming; peak: June 25, amplitude: 10.12%) (Figure S3h). The regions with the lowest amplitudes were

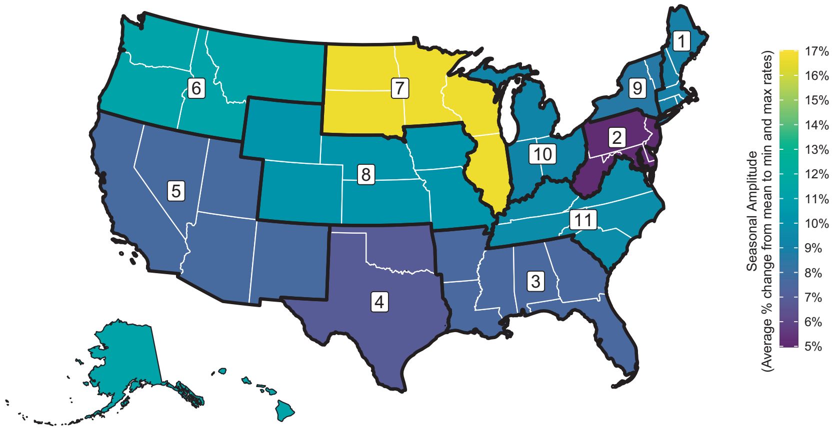

Figure 2 Geographical map of all 11 UNOS regions in the United States. Lighter colors reveal a greater seasonality effect amplitude from the midline. UNOS region 7, depicted in yellow, had the highest seasonal amplitude during the summer months. *Note:* Vermont is split between regions 9 and 1.

region 3 (Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, and Puerto Rico; peak: May 9, amplitude: 7.59%) (Figure S3c), region 4 (Oklahoma and Texas; peak: April 25, amplitude: 6.93%) (Figure S3d), and region 2 (Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, West Virginia, and Northern Virginia; peak: June 27, amplitude: 5.14%) (Figure S3b).

There was no significant difference in the odds of heart donation when comparing holidays +/- 7-days vs. non-holidays using the national data (odds ratio [95% CI]: 1.01 [0.98, 1.03], $P = 0.560$) or in any of the regional subsets (Table S2 and Table S3). A representative year (2016) of total daily hearts recovered for donation is depicted in Fig. 4.

Discussion

This study suggests that there is a significant increase in donor heart availability during the summer months, with the highest increase in UNOS Region 7 (Illinois, Minnesota, North Dakota, South Dakota, and Wisconsin). There was no discernable increase in organ availability during major U.S. holidays (New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, and Christmas Day).

It is speculated that an increase in donor hearts during the summer months is multi-factorial but driven primarily by injury-related deaths. Park *et al.* analyzed overall mortality in the United States between 1980 and 2016, whereby demonstrating higher overall mortality rates during the winter months and the lowest in the summer months in men and women ≥ 45 [5]. A similar study conducted by Davis *et al.* found consistent results [6]. However, this does not seem to be the case for adolescents and young adults, which demonstrated peak death rates in June/July and nadirs in December/January, driven primarily by fluctuations in injury-related deaths [5]. This may help explain the greater availability of viable hearts for transplantation during the summer months demonstrated in this study as more young donor hearts become available because of consequences of risky, warm weather-related activities. Homicides are likely not a contributor to this trend, as demonstrated by McDowall and Curtis who found no seasonal variation in homicide rates across large U.S. cities, thus suggesting minimal or no role in the seasonal effects of donor heart availability [7]. The higher donor heart availability in northern regions observed in our study may be due to increased engagement in risky behavior during warmer months, which is thought to occur less frequently or with little seasonal variation in other regions.

The findings of this study provide objective evidence that contrasts some commonly held beliefs regarding donor availability trends with respect to seasonality and U.S. holidays, namely, an anecdotal spike in donation surrounding U.S. holidays. The recognition of seasonal variations in donor availability begs the question of the clinical utility of this information, which unfortunately is unclear. Whether clinicians actually modify their behavior to potentially take advantage of an anticipated spike and thus optimize a patient's chance of an organ offer remains uncertain. Thus, we are left as to theorize how this information could be used for potential strategic waitlist modifications. One potential strategy is that clinicians could, within a specific month in which an increased availability is anticipated, selectively optimize waitlist patients such that in the event of a suitable organ offer, the patient is stable and in the best position to receive and recover well following a successful transplantation. Another theory is that these findings could inform listing strategies in stable LVAD patients with respect to the timing and utilization of 30-day EST time

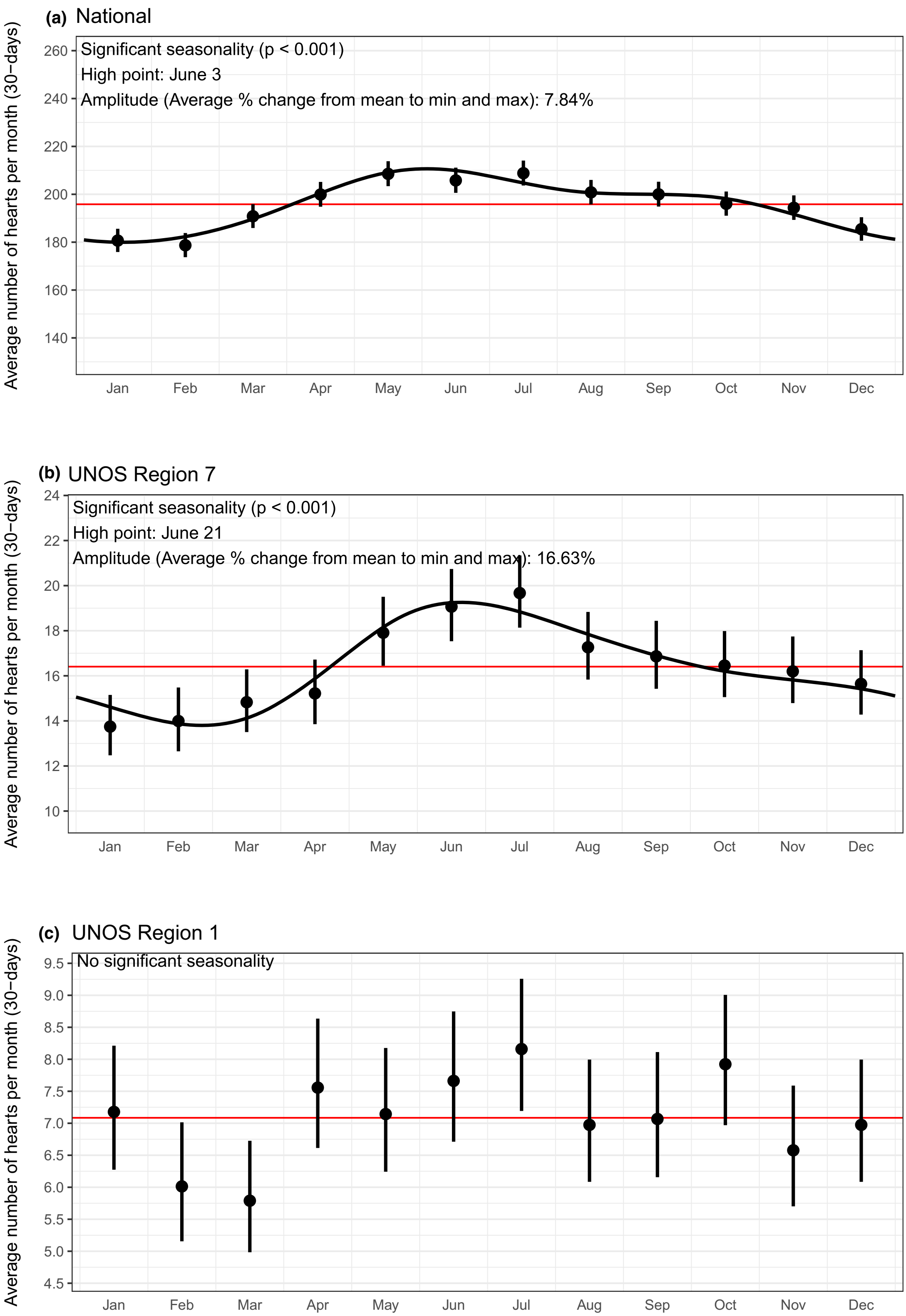

Figure 3 (a) Average number of hearts recovered nationwide from 1987 to 2017 for each month is plotted alongside a solid red line, which is the average number of hearts recovered nationwide for all months in the year. A significant seasonality ($P < 0.001$) effect was observed in the summer months displayed by the uptrend in heart availability in May, June, and July, with the peak rate falling on June 3 and peak amplitude of 7.84%. (b) The largest significant summer seasonality effect is plotted when looking at donor heart recovery in UNOS region 7. (c). UNOS region 1 displaying no significant seasonality effect when looking at donor hearts recovered.

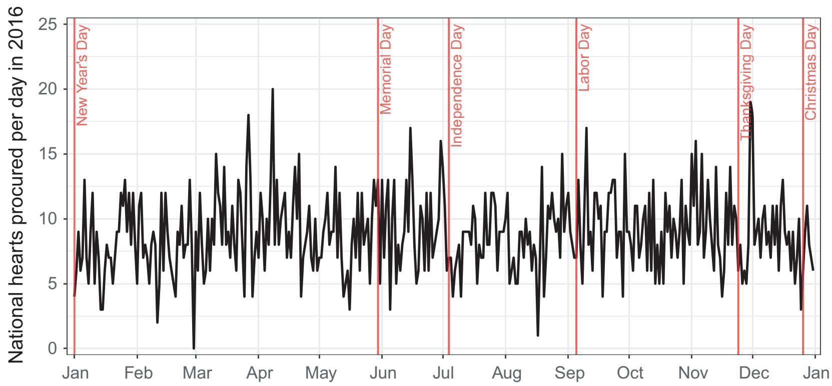

Figure 4 Representative year of daily heart recovery in 2016.

prior to or during periods of an anticipated increased availability. Currently, UNOS policy allows a 30-day window for patients with a dischargeable durable LVAD (Status 4) to be elevated to Status 3. The timing of this 30-day EST period may be critical for this population of patients given a temporarily increased priority. As of July 2020, there are 1466 status 4 patients, comprising 42.0% of waitlist patients [1]. Therefore, there is a substantial patient population who stands to be impacted by information about the strategic utilization of their EST.

The origins of 30-day EST reflects the evolution of LVAD technologies. Early generation LVADs demonstrated a significantly heightened risk of device-related complications compared with modern devices, resulting in the development of UNOS policies that allocated a period of higher priority status to these patients. In a 1999 revision, patients with LVADs could be listed as Status 1A (current system, status 1-3) if the device had been implanted for less than 30 days or a device-related complication occurred, such as infection, thromboembolism, mechanical failure or arrhythmia. This revision was because at the time LVAD patients had a 5-10% mortality *per week* [8]. In 2002, another revision was made allowing patients with an implanted left and/or right ventricular assist device to be listed for 30-days as Status 1A once the treating physician determined that the patient was clinically stable and did not require hospitalization. This 30-day Status 1A time was meant to minimize device-related complications, transplant high-risk patients sooner, and allow an interval of time for patients to recover after LVAD implantation before moving onto heart transplantation [8]. Advances in LVAD technology and improvements in patient management have increased survival and reduced device-related complications [3]. This was demonstrated in the pivotal MOMENTUM 3 trial comparing the latest generation of centrifugal-flow, durable LVADs with fully magnetically levitated bearing systems, to prior generation axial-flow devices. At two years follow-up, 76.9% of centrifugal-flow LVAD patients were alive and free of disabling stroke or reoperation to replace or remove a malfunctioning device compared with 64.8% of axial-flow devices ($P < 0.001$). Additionally, pump replacement was less common in centrifugal-flow LVAD patients (RR 0.21, $P < 0.001$) as were the incidence of stroke, major bleeding, and gastrointestinal bleeding [9]. In reality, not only are the rates of complication improving, but their nature is less threatening as in prior decades. Ultimately, outside of true device-related complications or failures, the current policy of 30-day EST listing does not truly reflect current clinical outcomes [10]. Therefore, the current policies may be outdated and a reflection of the limitations and detriments of prior technologies.

Based on these developments, controversy exists regarding the appropriateness of 30-day EST in the current era. In most instances, survival of patients implanted with durable LVADs as a bridge-to-transplant is approaching or comparable to those receiving de novo heart transplants [11–13]. A study of status 1B (current system, status 4) durable LVAD patients using EST showed similar 3-year post-transplantation survival rates compared with Status 1B patients not using EST. However, both of those groups had significantly greater survival when compared with LVAD Status 1A patients with device-related complications undergoing transplantation [14]. Longer waitlist times for both Status 1A and 1B patients could be to blame, as reported by Schulze *et al.*, who noted increasing waitlist times, most in excess of 30 days, both before and after 2006 UNOS allocation policy changes, thus contributing to geographic waitlist disparities and likely making 30-day EST of little strategic use with respect to securing an organ in a more timely fashion during a period of higher priority status [15]. While device-related complications are decreasing, 30-day EST may disadvantage durable LVAD patients who do experience a life-threatening device-related complication [9,13]. Uriel *et al.* found that as the wait time for transplantation increased and the percentage of patients being bridged to transplant with an LVAD increased, the majority were transplanted in the setting of device-related complication [16]. Additionally, while candidates with stable LVADs are at the lowest risk of adverse outcomes while on the waiting list, device-related complications are associated with an increased risk of death or delisting [3,8,13,14]. Thus, patients who are not as likely to benefit from a higher waitlist priority, such as stable patients using 30-day EST, potentially disadvantage these higher risk patients by being placed in similar priority category despite not being as clinically sick or at risk of adverse outcomes.

Conventional, anecdotal wisdom holds that transplant volume spikes during major U.S. holidays, but do not otherwise vary by seasonal trends. However, the existing data from a small number of studies is mixed on this point. One study assessed rates of heart transplant using the UNOS dataset from 2001 to 2010 and found a higher rate during the 4th of July and a higher likelihood of transplant during the summer and spring seasons [17]. Interestingly, there was no difference found in the daily percentage of Status 1A patients (current system, Status 3) transplanted between holidays and non-holidays suggesting likely no significant modification in listing practices globally despite commonly anticipated spikes in organ availability [17]. Another study found a significant upward trend in thoracic organ transplantation rates during the summer, on weekdays, and the week after July 4, with no increases around other major US holidays [18]. These differences could be due to variances in the time periods studied and application of differing statistical methodologies. We assumed the seasonal variance would follow a sinusoidal pattern and as such used a Poisson model with a cosinor term to find where the seasonal peak is during the year, instead of grouping months into four seasons and using a Poisson model. Furthermore, we used individual UNOS regions instead of grouping regions into larger categories (North, South, East, West), leading to more specific geographic conclusions. Our results do not support an advantage to increased odds of transplantations with listing during US holidays vs other dates, but a general increased availability during certain seasons.

A final consideration for EST time use is its impact on donor–recipient match quality. Nguyen *et al.* demonstrated a survival benefit for candidates of all waitlist designations for all donor risk index risk groups, but with the greatest benefit seen in Status 1A and 1B patients maximized with low-risk donors. This is most pronounced in Status 1A patients [19]. Survival benefit was seen shortly after transplantation in these patients [19]. Status 2 patients (current system, status 6), however, had a delayed survival benefit with excess mortality up to 51 months post-transplant. This is in line with findings that one-year cardiac transplantation survival is highest with the lowest donor–recipient risk score population [20]. Thus, it stands to reason that elevated priority status through usage of EST may divert low-risk organs away from those who would benefit the most (true Status 1A, or Status 3 patients) resulting in patients being transplanted who would do favorably with higher risk donors or with waiting [19].

Some limitations of the current study are that all hearts recovered for transplant are included, however a small proportion of recovered hearts were not transplanted (< 2%). The UNOS Deceased Donors dataset includes organ donations from September 1987 through March 2017 for all regions, except region 11, which contains data from January 1990 through March 2017. A 7-day window surrounding holidays was used, which we believe accurately represents the timeframe for hearts recovered during a major U.S. holiday, but variability does exist and consideration to the average time from patient admission to organ procurement could support a different time window, although to our knowledge supportive data to this is lacking in the current literature. The current study focused on the organ allocation system in the United States and therefore is not generalizable to other countries; however, a similar analysis for other countries using specific national or regional holidays to support or refute these findings could be performed in future studies. Finally, theorization of the clinical utility of seasonal and holiday variations are not answered by this study specifically, but primarily serve as thought provoking discussion points and will require further study tailored to answer whether clinicians modify practice according to either subjective beliefs or objective fact of donation variation or whether strategic utilization of EST in LVAD patient occurs and whether it is of any clinical benefit.

Conclusion

Analysis of UNOS/OPTN registry data regarding heart donor availability demonstrated that during a 30-year interval there was no observable correlation between organ availability and U.S. holidays. However, in all UNOS regions except region 1, a significant seasonality

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effect was observed with higher donation rates occurring during warmer weather months. The regions with the highest amplitudes during the summer were northern regions. These findings may add another consideration to the strategic decision making behind transplant listing, specifically, utilization of 30-day EST for stable LVAD recipients and the optimization of current patients on the waiting list.

Authorship

M.A.K. was lead author in study design, manuscript drafting, and data analysis. N.J.S. assisted with data analysis, manuscript drafting and editing, and study advising. L.R. was the primary statistician and performed all statistical analysis. A.R., B.M., L.D.J., and A.M. were vital in manuscript preparation and editing. D.L.J. was the study primary investigator and principle advisor.

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Conflicts of interest

None of the authors listed have any conflicts of interest to disclose in the submission of this manuscript.

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SUPPORTING INFORMATION

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

Table S1. Seasonality model regression coefficients.

Table S2. Holiday window sensitivity analysis.

Table S3. Holiday window sensitivity analysis – Regional.

Figure S1. Plot of spline terms.

Figure S2. Serial sections analysis of seasonality trend across years.

Figure S3. Annual heart donation trends by region.

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