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ORIGINAL ARTICLE

Donor predictors of allograft utilization for pediatric heart transplantation

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SUMMARY

Pediatric heart transplantations are limited by the supply of donor allografts. We sought to determine the cardiac allograft utilization rate for pediatric donors and identify donor factors that predict graft use for transplantation. The United Network for Organ Sharing deceased donor database was queried from April 30, 2006, to March 31, 2014. Donor risk factors that might affect graft use for cardiac transplantation were evaluated. The pediatric cardiac graft utilization rate was calculated, and logistic regression modeling was performed to determine the relationship of risk factors with graft use for transplantation. During the study period, 6682 eligible cardiac donors <18 years of age were identified, and 3758 (56.2%) grafts were utilized for transplantation. Grafts from male donors (OR 1.181) were significantly associated with graft utilization. Graft donor age >1 year (OR 0.363), non-O blood type (OR 0.586), CDC 'high-risk' donor status (OR 0.676), use of inotropes (OR 0.718), use of >2 inotropes (OR 0.328), and donor left ventricular ejection fraction <50% (OR 0.045) were significantly associated with graft nonutilization. The pediatric cardiac allograft utilization rate and risk factors for graft use for transplantation have been identified. Additional studies will be needed to assess the donor–recipient relationship on pediatric transplant outcomes.

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Introduction

Despite improvements in outcomes for children needing heart transplantation in the current era, transplant waitlist mortality remains unacceptably high. Pediatric heart transplant waitlist mortality may be as high as 17% [1] and even higher in infants, and those with congenital heart disease [2]. While improving public awareness and consent rates for organ donation in the United States (US) will help increase the donor pool, attention must also be paid to identifying factors limiting the utilization of cardiac allografts from consented organ donors.

Many pediatric centers continue to use stringent adult donor criteria to determine suitability of cardiac grafts, given the paucity of pediatric-specific studies that link donor factors to recipient outcomes after transplantation. While numerous recipient factors have been associated with post-transplant outcomes, very few donor factors have been shown to have any effect on post-transplant outcome in the pediatric population [3]. Furthermore, at this time, it is unknown what donor-specific factors affect cardiac allograft utilization for transplantation in children.

The specific aims of this study were to determine the percentage of eligible pediatric cardiac allografts that are

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utilized for transplantation and to identify donor-specific risk factors that predict allograft use for heart transplantation. Although only a few donor factors are suggested to affect post-transplant outcomes in children, we hypothesize that several donor demographic, clinical, and graft factors would be significantly associated with cardiac graft utilization in pediatric transplantation.

Materials and methods

The United Network for Organ Sharing (UNOS) deceased donor database was searched from April 30, 2006, to March 31, 2014, to identify all eligible pediatric donors of cardiac allografts. For the purposes of this study, an eligible cardiac allograft was defined as any graft from a patient less than 18 years of age who had consent obtained for cardiac graft donation, regardless of the outcome of that consent. The UNOS deceased donor database sorts all organ donors into 6 categories based on their cardiac graft donation disposition: (i) consent for cardiac graft donation not requested, (ii) consent for cardiac graft donation not obtained, (iii) consent obtained but cardiac graft not recovered, (iv) cardiac graft recovered, but for reasons other than transplant, (v) cardiac graft recovered for transplant, but not transplanted into a recipient, and (vi) cardiac allograft transplanted into a recipient. We excluded all donors without consent for cardiac graft donation (i & ii). We considered a graft eligible if consent was obtained for cardiac donation (iii–vi). We considered all eligible grafts not transplanted into a recipient (iii–v) as 'nonutilized' and this included cardiac allografts that were consented for donation but not recovered, were recovered but used for other purposes such as research, as well grafts that were discarded after recovery. Cardiac grafts transplanted (vi), regardless of recipient age or outcome of transplant, were considered 'utilized'. We calculated the cardiac allograft utilization rate as the number of allografts utilized for transplantation out of all eligible cardiac grafts.

Next, we looked at several donor-specific 'risk factors' that might predict graft utilization based on previous studies investigating donor factors and transplant recipient outcome. Donor risk factors selected in this study were somewhat different from risk factors that have been studied previously in the adult population. Donor risk factors associated with graft nonutilization in adult cardiac transplantation such as diabetes, hypertension, drug abuse, coronary artery disease, and death via cerebrovascular accident are rare in the pediatric population and thus were not selected for this study [4]. We chose our risk factors based on three broad categories applicable to children that are found in the UNOS deceased donor database: donor demographics, donor clinical history/status, and cardiac graft status. Donor demographic data included gender, age (dichotomized into age <1 year old versus >1 year old groups), and blood type (blood type O versus non-O). For donor clinical data, we looked at the Center for Disease Control (CDC) 'high-risk' donor status, cytomegalovirus (CMV) status, Epstein–Barr virus (EBV) IgG status, as well as the presence of a bacterial clinical infection in the donor. Finally for graft status, we investigated left ventricular (LV) ejection fraction (EF) prior to donation (dichotomized into EF >50% or normal versus EF <50% or abnormal), the use of any inotropes, or >2 inotropes in the eligible donor prior to donation as risk factors for cardiac graft utilization.

The prevalence of each risk factor in the groups of utilized and not-utilized grafts was calculated and chi-squared analysis was performed. Next, binary logistic regression modeling was performed to measure the relationship between the donor risk factors and cardiac allograft utilization for transplantation. The odds ratio and 95% confidence intervals were generated for each risk factor. The c-statistic was then calculated to measure the predictive accuracy of the logistic regression model. In addition, post hoc analysis was performed to further investigate several of the individual risk factors using chi-squared analysis or repeated logistic regression modeling. All statistical analysis was performed using SPSS version 20. A P-value less than <0.05 was deemed significant.

Results

During the study period, there were 6682 eligible cardiac allografts, and 3758 allografts were used for transplantation giving a graft utilization rate of 56.2%. The prevalence of each of the donor risk factors and their association with the utilized and nonutilized groups are shown in Table 1. Of note, several donors were missing data from 1 or more risk factors, with missing data prevalence ranging from 0% to 19.5% per risk factor.

Five thousand two hundred and fifty-nine donors (78.7%) had all data present for logistic regression modeling. Donor male gender (OR 1.181, CI 1.013–1.378, $P = 0.034$) was significantly associated with graft utilization for transplantation (Fig. 1). Conversely, donor age >1 year (OR 0.363, CI 0.281–0.467, $P < 0.001$), non-O blood type (OR 0.586, CI 0.503–0.682, $P < 0.001$), CDC 'high-risk' donor status (OR

Table 1. Prevalence of donor risk factors in utilized and nonutilized cardiac allografts and univariable chi-squared analysis.

	Donor factor	Nonutilized N = 2924, 43.8%	Utilized N = 3758, 56.2%	Missing	P-value
Demographics	Age >1 year	2679 (91.6%)	3067 (81.6%)	0 (0%)	<0.001
	Male gender	1760 (60.1%)	2428 (64.5%)	0 (0%)	<0.001
	Non-O blood type	1655 (56.6%)	1781 (45.6%)	1 (0%)	<0.001
Clinical	EBV IgG+	1882 (64.3%)	2517 (66.9%)	825 (12.3%)	0.43
	CMV+	1521 (52.0%)	2023 (53.8%)	39 (0.6%)	0.107
	Clinically infected donor	1426 (48.7%)	2006 (53.3%)	145 (2.2%)	<0.001
	CDC 'high-risk' donor	139 (4.7%)	168 (4.4%)	10 (0.1%)	0.63
Graft	LV EF <50%	873 (29.8%)	145 (3.8%)	1306 (19.5%)	<0.001
	Inotropic support	1606 (54.9%)	1864 (49.6%)	27 (0.4%)	<0.001
	>2 inotropes used	224 (7.6%)	60 (1.5%)	0 (0%)	<0.001

EBV IgG, Epstein–Barr virus IgG; CMV, cytomegalovirus; CDC, Center for Disease Control; LV, left ventricular; EF, ejection fraction.

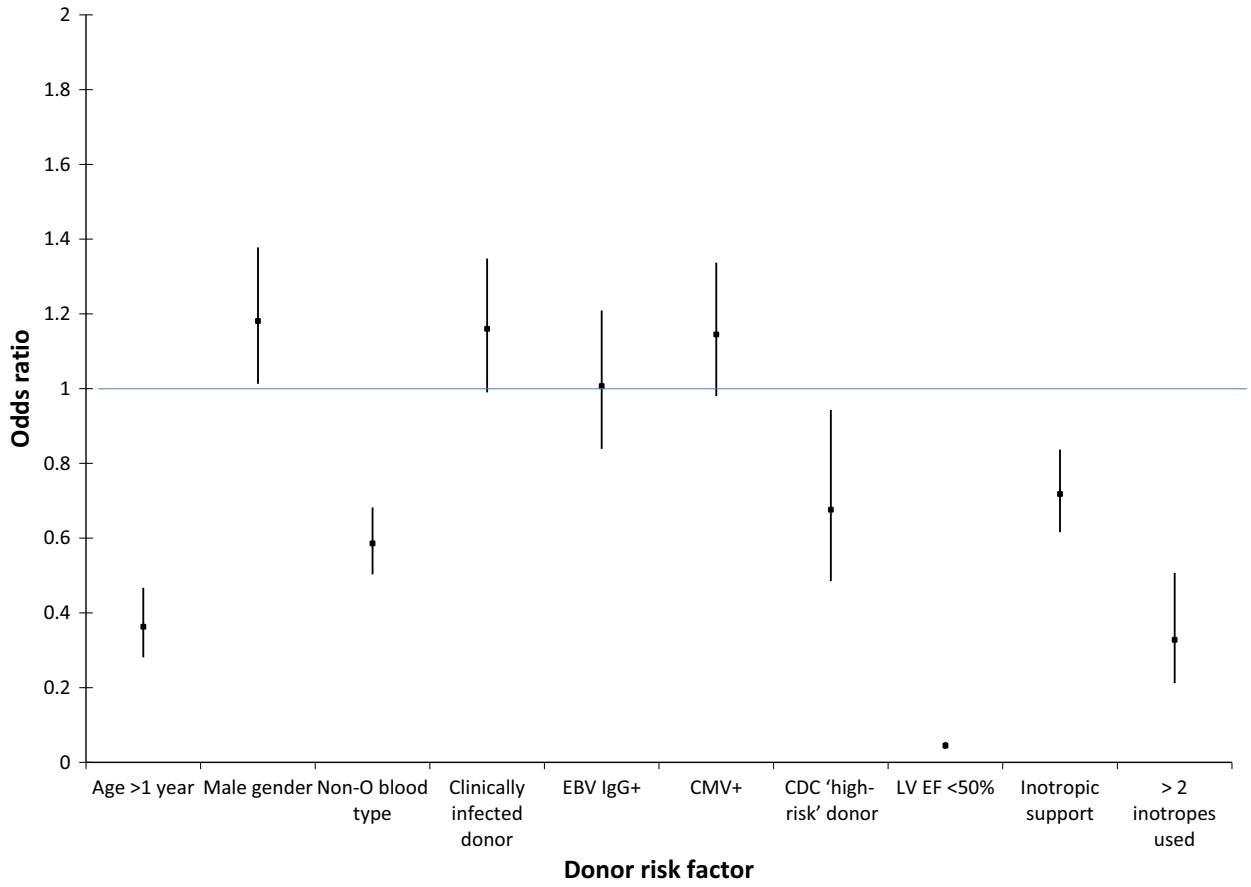

Figure 1 Logistic regression modeling of donor risk factor association with cardiac allograft utilization for transplantation in children. LV, left ventricular; EF, ejection fraction.

0.676, CI 0.485–0.943, P = 0.021), LV EF <50% (OR 0.045, CI 0.036–0.055, P < 0.001), inotropic support (OR 0.718, CI 0.616–0.837, P < 0.001), or use of >2 inotropes in the donor (OR 0.328, CI 0.212–0.507, P < 0.001) were significantly associated with graft nonutilization. Donor clinical infection (OR 1.160, CI 0.998–1.348, P = 0.053), CMV positivity (OR 1.145, CI 0.980–1.337, P = 0.089), and EBV IgG positivity (OR 1.007, CI 0.839–1.209, P = 0.941) did not have any significant association with graft utilization. Finally, the

predictive accuracy of the logistic regression model, as measured by the c-statistic, was 0.796 (CI 0.782–0.811, $P < 0.001$).

Various types of subgroup analysis were performed. Grafts from O-type donors remained significantly more likely to be utilized for transplantation than grafts from non-O-type donors (61% vs. 54%, chi-squared $P = 0.038$) after ABO incompatible transplants were expanded after 2010. When removing infants <1 years old from risk factor analysis due to potential transplacental transfer of maternal antibodies, EBV IgG and CMV seropositivity still remained nonsignificant in repeated logistic regression modeling (OR 1.055, CI 0.867–1.285, $P = 0.593$ and OR 1.152, CI 0.976–1.361, $P = 0.095$ respectively). Donors with missing quantitative assessment of LV EF (19.5% of all eligible donors) were disproportionately associated with graft nonutilization (87% nonutilized vs 13% utilized). Lastly, in interaction analysis, there was no significant interaction effect between any inotrope use and multiple inotropes use (OR 0.465, CI 0.077–2.795, $P = 0.403$), or LV EF <50% and any inotrope use (OR 0.975, CI 0.636–1.496, $P = 0.908$).

Discussion

Graft utilization rate

During the study period, 56.2% of all available pediatric cardiac allografts in the United States were utilized for transplantation. This utilization rate is higher than the 43% utilization rate reported in adult cardiac transplantation from a recent regional study [4] but lower that the 65.7% utilization rate reported by Bailey *et al.* [5] from an earlier cohort. From a global perspective, this rate is fairly similar to the 60% cardiac allograft utilization rate extrapolated from data on 65 donors of any organ for children aged 0–15 from the 2015 Eurotransplant report [6]. To our knowledge, however, this is the first report of the utilization rate for pediatric cardiac allografts from donors that specifically consented to cardiac donation in the United States. Also the pediatric cardiac allograft utilization rate is also lower than the 65–88% that has been reported in the literature for transplantation of other solid organs [7]. We speculate the cardiac allograft utilization rate of 56.2% is lower when compared to that of other solid organs due to the limiting factors potentially unique to cardiac transplantation, such as recovery distance from recipient and stringent cardiac graft functional parameters.

Risk factors for graft utilization

Of the donor demographics, gender, age and blood type, each had a significant positive or negative association with graft utilization. The increased utilization rate of grafts donated by males is similar to what has been shown in adult transplantation [4]. The reasons for higher male donor graft utilization found in the pediatric population are unclear. In adult cardiac transplantation, there is a concern for donor–recipient size discrepancies, as well as hormonal and immunologic factors that may contribute to reduced recipient survival with cardiac grafts from females. These factors may contribute to the higher female graft discard rate reported [8]. These results have not been consistently replicated in pediatric literature. Recipients of female donor hearts have previously been reported to have worse outcomes and increased mortality in the pediatric population [9]. However, a recent report from Tosi *et al.* [10] looking at the effect of gender and gender mismatch on pediatric heart transplant outcomes found that while female recipients had overall worse outcomes, the donor gender itself did not have any significant effect on survival for male or female recipients.

We also found lower utilization for grafts from donors >1 year of age when compared to young infants, which was an expected finding. We chose to dichotomize age into two populations (<1 and >1 years old) because they generally represent two populations with different needs and urgency for transplantation. In general, older children are more likely to be listed for transplantation due to an underlying cardiomyopathy, whereas young infants are more likely need transplantation due to congenital heart disease [11]. Furthermore, since availability of grafts for recipients <1 year of age is infrequent (14% of all pediatric grafts available), and because infants have higher waitlist mortality [2], there is likely a pressure to increase the relative utilization of this rare resource for those at the highest risk.

Non-O blood type was found to be significantly associated with graft nonutilization. This too was an expected finding for several reasons. It is also possible that for donors with non-O blood types, there are fewer or no children on the waitlist with the same blood type and similar body surface area in that region, thus leaving the otherwise suitable non-O-type graft nonutilized. Furthermore, group O is the most common blood type and can potentially be transplanted in recipients with any blood type; thus, one would expect a higher utilization of blood type O grafts. Furthermore, in subgroup analysis, even after ABO incompatible transplants were

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expanded in UNOS 2010, grafts from O-type donors remained significantly more likely to be utilized for transplantation than grafts from non-O-type donors.

Neither donor clinical infection, CMV positivity, nor EBV IgG positivity was significantly associated with graft utilization in our model. This finding has not been seen nor evaluated with respect to pediatric cardiac graft utilization in other studies to our knowledge. It was surprising there was not an association with graft nonutilization with CMV-positive grafts because donor CMV seropositivity has been associated with worse post-transplant outcome for CMV-negative recipients [12]. We postulate that the lack of association with nonutilization may be due to the relative frequency of CMV-positive donors and the availability of effective CMV post-transplant prophylaxis when considering CMV-positive donor allograft for transplant. In addition, EBV IgG positivity also did not have an association with graft nonutilization. We predicted that due to concerns of the possibility of post-transplant lymphoproliferative disorder in the recipient, that EBV IgG-positive donor grafts would be less likely to be utilized. However, our data does not support that prediction. Again, the relative high frequency of EBV IgG-positive donors in the population might play a role in the lack of a significant association with graft utilization. In subgroup analysis, even when removing infants <1 years old who may have seropositivity for EBV IgG or CMV due to maternal placental transfer, both risks factors still remained nonsignificant in repeated logistic regression modeling.

The UNOS donor database defines a donor clinical infection as a bacterial infection in the blood, urinary, or respiratory tracts as confirmed by culture. To our knowledge, this does not include viral or fungal infections and also does not include seropositivity for CMV or EBV as an active clinical infection of a donor. In our analysis, we found that donor clinical infection was not associated with graft utilization for transplantation. This was a somewhat unexpected finding as we thought transmission of a pathogen from any type of infection would pose a risk to an immunocompromised recipient after solid organ transplantation. A recent report suggests that the number of donor-derived disease transmission reported to UNOS has increased steadily, most likely due to improved reporting [13]. While the incidence of donor transmission of an infection to the recipient remains low with organ donation (0.96%), the few reported transmission events have resulted in significant morbidity and mortality in recipients [13]. Furthermore, a study looking retrospectively at organ donors found bacteremia in 5% of the donor population [14]. However, despite the theoretical risks of transmission of a bacterial pathogen into an immunosuppressed recipient and worse outcomes in cases of reported transmission events [13], we did not find an association with donor clinical infection with graft utilization for transplantation. The type and severity of donor infection may be an important consideration when evaluating a graft for transplantation, but there is a lack of specificity about this risk factor in the UNOS deceased donor database, and this finding could not be further explored in this study.

Not surprisingly, CDC 'high-risk' donor status had a significant association with graft nonutilization. A survey done after a highly publicized case of HIV and hepatitis C transmission to 4 adult transplant recipients in 2007 found that a third of the surgeons reported altering their practice and 41% of these reported decreasing or stopping use of 'high-risk' donor organs [15]. It is therefore not surprising that CDC 'high-risk' donor status was found to have a negative impact on graft utilization. This small donor population (4.6% of all donated pediatric grafts) is a potential source for additional transplantations. In a study by Sahulee *et al.* [16] looking at the UNOS database, pediatric recipients of CDC 'high-risk' donor grafts did not have any significant differences in mortality, post-transplant length of stay, or predischarge episodes of rejection. In the pediatric population, we assume most of the CDC 'high-risk' donors were infants born to mothers at risk for HIV infection via the behavioral criteria for adult donors, and the pediatric donor grafts were therefore not considered to be truly at high risk for disease transmission for transplantation, despite the UNOS classification. However, it is important to note that there is no subclassification within UNOS to stratify the CDC 'high-risk' group into those listed as high risk due to maternal history versus those listed as high risk from exposure from transfusions or personal behavior.

Graft factors had among the strongest associations with donor graft utilization, and most significantly, donor graft LV EF had the greatest impact on graft utilization for transplantation. We found that LV EF <50% prior to organ donation is the strongest predictor for graft nonutilization. However, a few pediatric studies have shown that depressed systolic function in the cardiac allograft is not associated with decreased recipient survival [17,18]. Specifically, Rossano *et al.*'s [18] recent review of the UNOS database revealed that even moderately depressed LV function of the donor graft was not associated with any significant difference in survival in the recipients. It is important to note, however, that a

quantitative reporting of donor graft systolic function in the UNOS database was inconsistent, with nearly 1/5 of the donors missing quantitative assessment of LV EF. On further analysis, donors with missing quantitative assessment of EF were disproportionately associated with graft nonutilization, potentially affecting the strength of association in our logistic regression modeling. Furthermore, we also found that the need for inotropes or multiple inotropes in the donor strongly predicts graft nonuse for transplantation. It is known that after brain death, there is a neurohormonal imbalance that eventually leads to depressed systolic function and lower blood pressures [19]. In many centers, potential donors are placed on inotropes or vasopressors for this particular reason. In other centers, inotropes or vasopressors are initiated prophylactically. Given this expected course after brain death, it is certainly plausible that otherwise suitable grafts being supported with inotropes are being underutilized for transplantation due to perception of graft inadequacy, when the donor graft may only need to be supported transiently. In support of this hypothesis, in post hoc analysis there was not an interaction effect between inotrope use and multiple inotropes use, nor LV EF <50% and inotrope use. Although this may suggest inotrope use in a donor may not be specifically due to abnormal systolic function, it is important to note that LV EF and inotrope use at time of donation are not simultaneously recorded in UNOS, thus limiting the strength of this speculation.

Some investigators that have looked at regional or national databases suggest that few donor-specific factors predict any significant difference in recipient survival [4,20,21]. In fact, most studies have found that recipient factors are the strongest predictors of transplant outcome [22,23]. With donor-specific factors associated with graft utilization identified, further studies will be needed to be able to demonstrate the relationship of donor factors, or multiple donor risk factors, with differences in recipient outcome in children. If it is proven that few donor-specific risk factors contribute to recipient outcome, potentially there would be an opportunity to increase our use of grafts from donors with characteristics that would otherwise predict nonutilization. In support of this hypothesis, a handful of studies have suggested that grafts with 'less than optimal' quality have competitive outcomes and should be considered for use for the vulnerable population awaiting cardiac transplantation [5,18]. Specifically, Lima *et al.* [21] showed that adults who received cardiac grafts with marginal or high-risk characteristics have demonstrated competitive outcomes to standard risk grafts. While a few pediatric centers are utilizing an alternate listing method for high-risk patients, the concept of alternate listing has not yet been uniformly adopted for the pediatric population. Given the promising outcomes in the adult population, this concept merits debate as a possible way to increase transplantation volume in the pediatric population. By increasing the rate of graft utilization, we can increase our volume of transplantation and thus decrease the waitlist times and waitlist mortality for those children needing heart transplantation.

This study has several important limitations due to its design. First, a retrospective study using a large nationwide database is dependent on accurate and complete data entry. Second, due to the quality of data entry, we were limited to the number of risk factors that we were able to investigate without large proportions of missing or incomplete data. Additionally, several additional variables that may play a role in determining the disposition of an available graft, such as cross-match or ischemic time, could not be evaluated since these details were not available in the donor database for grafts that had been offered for transplant but were not accepted. A further limitation of this study is the inability to comment on recipient characteristics and outcomes. This study utilized the UNOS deceased donor database to investigate the donor characteristics that predict graft use for transplantation and therefore does not include recipient data to associate with post-transplant outcome. It is possible that recipients transplanted with grafts with several donor risk factors had different waitlist characteristics than those who received 'standard risk' grafts, and thus may have had different post-transplant outcomes. This determination is beyond the scope of this study and could not be made given the limited information available in the UNOS deceased donor database.

In conclusion, 56.2% of all eligible donated pediatric cardiac allografts are utilized for transplantation. Donor male gender was associated with increased graft use for transplantation, whereas donor age >1, non-O blood type, CDC 'high-risk' status, graft EF <50%, the need for inotropic support, or >2 inotropes in the donor predicted graft nonutilization for heart transplantation. Further pediatric studies will need to determine whether transplantation of cardiac grafts with one or more donor 'risk factors' translates to differences in transplant recipient morbidity and mortality.

Authorship

AMK: data analysis, drafting article, critical revision of article, approval of article, and data management. RSG:

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statistics, critical revision of the article. IDL: drafting of article, critical revision of article, and approval of article. RS: design, data analysis and interpretation, drafting of article, critical revision of article, approval of article, statistics, and data collection/management.

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Conflict of interest

The authors have declared no conflicts of interest.

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