Donor Risk Factors Affecting Graft Survival in Pediatric Kidney Transplantations: Protocol for a Systematic Review and Meta-analysis

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Abstract

Background: Pediatric patients with end-stage kidney disease require kidney transplants (KT) throughout their lifetime. Long-term graft survival is dependent on multiple factors which are broadly categorized as donor and recipient related factors. Advances in transplant care and changes in donor population demographics necessitate an updated analysis on donor risk factors to guide clinical decision making.

Objective: In this systematic review/meta-analysis, we will focus on the impact of donor factors on graft survival in pediatric KT, excluding transplants from donation after circulatory death as the latter are less common in children.

Methods: This review encompasses studies reporting donor-related risk factors for graft survival in pediatric KT, including age, size, comorbidities, and ethnicity for living and deceased donors, also the cause of death and length of hospitalization for deceased donors. The literature search will use databases including PubMed, Scopus, Web of Science, Embase, and Cochrane. Two independent reviewers will select studies and assess their quality. Pooled estimates of relevant factors will be computed via a random-effects model using Stata/BE 18 software. Depending on data availability, the subgroup analyses will be conducted based on factors such as donor type (living versus deceased) and age group. The reporting of findings will adhere to the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines.

Results: The search and screening for the systematic literature review are anticipated to be finished in August 2025. Data extraction, quality appraisal, and subsequent data synthesis will begin in September 2025. The review is expected to be completed by April 2026, and the study results will be published in 2026.

Conclusions: Our review will provide a comprehensive synthesis of the available evidence on kidney donor risk factors impacting graft survival in pediatric KT. The results of this review could provide valuable insights for clinical decisions, policy development, and ongoing efforts to improve outcomes for children with end-stage kidney disease requiring KT. Clinical Trial: PROSPERO CRD42024500442. https://www.crd.york. ac.uk/prospero/display_record.php?ID=CRD42024500442

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Abstract

Background: Pediatric patients with end-stage kidney disease require kidney transplants (KT) throughout their lifetime. Long-term graft survival is dependent on multiple factors which are broadly categorized as donor and recipient related factors. Advances in transplant care and changes in donor population demographics necessitate an updated analysis on donor risk factors to guide clinical decision making.

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and age group. The reporting of findings will adhere to the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines.

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Conclusion: Our review will provide a comprehensive synthesis of the available evidence on kidney donor risk factors impacting graft survival in pediatric KT. The results of this review could provide valuable insights for clinical decisions, policy development, and ongoing efforts to improve outcomes for children with end-stage kidney disease requiring KT.

Trial Registration: PROSPERO CRD42024500442. https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42024500442

Keywords: age factors, diabetes, height, hla, mismatch, hypertension, smoking

Introduction

End-stage kidney disease (ESKD) imposes profound challenges to the health and well-being of pediatric patients and their families [1– 4]. Among the treatment options for ESKD, kidney transplantation (KT) is the most preferred, demonstrating better outcomes with reduced mortality and morbidity [5–8]. Additionally, pediatric KT creates opportunities for improved growth, development, education, and social interaction, leading to an overall enhanced quality of life for young recipients [1]. Pediatric transplant recipients are projected to live over 50 years and will therefore require more than one transplant during their lifetime. Minimising the need for multiple transplants and maximising the lifetime of each transplant is therefore crucial. Acknowledging the multiple risk factors including both medical and psychosocial factors, we aim to examine donor related factors

that affect long-term allograft survival. The effects of human leukocyte antigens (HLA) mismatching have previously been reviewed [9].

Prognostication is important to guide clinical decision making both at the population level as facilitated by kidney allocation schemes (KAS) and at the patient level as informed-decision making between the patient and clinical team. When a kidney offer is presented to a pediatric patient, nephrologists and transplant surgeons must rapidly make intricate decisions regarding the organ's suitability for transplantation. This process entails evaluating various clinical, psychological, and social factors, relying on often incomplete information about the donor and existing knowledge about the patient from the Organ Procurement Organization [10, 11]. Factors known to influence decisions include donor quality, recipient risk factors, and physicians' decision-making behaviors [9, 12–17]. Nonetheless, trying to weigh up each factor is difficult. Clinical risk indices which combine multiple factors have been developed but they have mainly used adult population data and their applicability in pediatric patients have not been proven [13, 18–20].

The increasing demand for KT among pediatric patients far surpasses the limited supply of organs from deceased donors, highlighting the necessity to expand the donor pool [21, 22]. The scarcity of kidney allografts poses a significant obstacle for ESKD patients seeking transplantation, emphasizing the crucial need to expand the donor pool and optimize the utilization of available allografts [22]. Additionally, the demographics of the donor population have changed and donors are becoming increasing older with more co-morbidities [13, 21]. Health care professionals therefore need to able to make careful considerations on accepting donors with risk factors rather than wait for an ideal donor which might prolong waiting times [13]. This review aims to examine donor risk factors and their impact on graft survival in pediatric KT patients. By combining recent evidence, it seeks to offer valuable insights for clinical decisions, policy development, and ongoing efforts to improve

outcomes for this vulnerable patient group. Our review aimed to answer the following question: In pediatric kidney transplantation, what are the donor risk factors which affect allograft survival?

Methods

This review will be conducted and reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocol guidelines (S1 Checklist). We will also integrate this review with the Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines since the outcome will be a meta-analysis of selected observational studies.

Eligibility criteria

We will include all original articles in English as follows;

1. Studies involving pediatric patients as kidney transplantation recipients (aged < 18 years old at the time of transplant).
2. Studies reporting the first kidney-only transplants from living donors (LD) and deceased donation after brain death (DBD).
3. Studies that investigate donor-related risk factors for graft survival and report graft survival as the primary or secondary outcome.
4. Peer-reviewed original articles, including randomized controlled trials (RCTs) and observational studies (cohort, case-control, and cross-sectional studies).
5. Published articles or accepted for publication beginning from 2000.

The exclusion criteria are;

1. Studies involving adult recipients in which the pediatric group data could not be extracted.
2. Studies involving transplants from deceased donors following circulatory death (DCD) in which the DBD group data could not be extracted.

3. Studies involving multi-organ transplants, in which the single-kidney-only group data could not be extracted.
4. Studies involving kidney re-transplantations in which the first kidney transplant group data could not be extracted.
5. Any review, case study, commentary, qualitative studies, or editorials.

Outcome measures

The following are the outcomes of this review:

- Death-censored graft survival: Graft survival, considering only cases where graft failure occurred due to factors other than patient death. Graft survival is defined as the time from transplant to graft failure. Graft failure is defined as the start of dialysis or re-transplantation.
- All-cause graft survival. Combined outcome of graft survival and patient survival.

Information sources

Electronic search

We will systematically conduct a comprehensive literature search using various literature databases, including MEDLINE (Pubmed), Web of Science, Scopus, Embase, and Cochrane Central Register of Controlled Trials (CENTRAL) to identify eligible studies. Secondary searches will be conducted on Google Scholar and other websites, and the reference section of the included studies will also be hand-searched for additional relevant studies. Studies will be restricted to the English language. The search will be performed from selected electronic databases up to July 2025..

Search strategy

The proposed search term for the first theme will be “pediatric kidney transplantation”, including keywords for children and adolescents. The second theme is “risk factor”, including unrelated, living,

or tissue donor, and donor selection. The third theme is “graft survival”. The exploded versions of the Medical Subject Headings (MeSH) for each theme will be included. All three search themes will be combined using the Boolean operators “OR” and “AND. The detailed search terms for each database are presented in **Table S1.**

Study selection

We will identify and remove duplicates and collate multiple reports. Two review authors will independently screen all the titles and abstracts to examine the potential studies for inclusion and exclude studies which are clearly irrelevant. We will identify the studies and code them as “retrieve” (eligible or potentially eligible/unclear) or “do not retrieve”. We will retrieve the full-text study reports and publications, and the review authors will independently screen the full text to identify studies for inclusion, as well as identify and record reasons for the exclusion of the ineligible studies. We will resolve any disagreement through discussion. If no consensus is reached, the other two authors will act as arbiters.

We will record the selection process in sufficient detail to complete a PRISMA flow diagram and construct a table describing the characteristics of the excluded studies [23, 24]. The EndNote Reference Management Software will be used to store, organize, and manage all the articles identified from databases.

Data extraction and management

We will use a standardized data extraction form created by the Microsoft Excel Spreadsheet Software for study characteristics and outcome data. Two review authors will independently extract outcome data from the included study. We will note in the “characteristics of included studies” table if outcome data is not reported in a usable way. We will resolve any disagreements by consensus or by

involving the two other authors. We will double-check that data is entered correctly by comparing the data present in the systematic review with the study reports. The following study characteristics from the included studies will be extracted;

- Title, authors, study country, region, and publication year.
- Methods: study design, source of data, total duration of the study, and method of analysis.
- Participants: number of patients (n), age range, and sex.
- Outcome: graft survival.
- Exposures or risks: donor age, sex, diabetes, hypertension, smoking, body height, body weight, ethnicity, cause of death, days in hospital, CMV, and HCV. However, whenever data is applicable, we will extract the data on other exposure risks or modifiable risk factors, control conditions, and adjustment variables.

Quality assessment.

Two review authors will independently assess the study's quality based on the criteria in the Newcastle-Ottawa Scale (NOS) for observational studies. The NOS is a widely used tool for assessing the quality of non-randomized studies, including cohort studies and case-control studies. The NOS applied a "star system," where the study is assessed based on three broad perspectives: 1) the selection of the study groups; 2) the comparability of the groups, and 3) the ascertainment of exposure and outcome [25]. The maximum score is 9 points, where the studies can be classified as good, fair, or poor quality according to the following standard thresholds; -

1. Good quality: 3 or 4 stars in the selection domain AND 1 or 2 stars in the comparability domain AND 2 or 3 stars in the outcome/exposure domain.
2. Fair quality: 2 stars in the selection domain AND 1 or 2 stars in the comparability domain AND 2 or 3 stars in the outcome/exposure domain.
3. Poor quality: 0 or 1 star in the selection domain OR 0 stars in the comparability domain OR 0

or 1 star in the outcome/exposure domain.

To assess the risk of bias in the included intervention studies, we will use the Cochrane Risk of Bias Assessment Tool: for Non-Randomized Studies of Interventions (ACROBAT- NRSi) tool [26]. This assessment tool consists of five domains of bias, including selection bias, confounding bias, performance bias, detection bias, and attrition bias, which will be assessed using a set of signalling questions. Each domain will be rated as having a low, high, or unclear risk of bias, and an overall risk of bias rating will be assigned for each study. The use of the ACROBAT- NRSi tool will allow us to provide a standardized assessment of the quality of evidence from non-randomized studies of interventions and to determine the overall risk of bias across studies.

Statistical analysis

Data analysis and statistical analysis

Statistical analyses will be conducted using Stata software. The main R packages, “meta” and “metafor”, will be used for meta-analysis. We will calculate the pooled estimates of graft survival using a random effect model to allow for heterogeneity across studies. Whenever data is applicable, we also plan to perform the stratification of estimates by donor type (living donor versus deceased donor) and age group.

Assessment of heterogeneity

Assessing heterogeneity is a critical step in conducting a meta-analysis, as it allows for an evaluation of the degree of inconsistency or variability among the results of individual studies. For this review, we will evaluate heterogeneity using both the I^2 and Q statistics. The I^2 statistic will be used to quantify the impact of heterogeneity, with percentages of around 25%, 50%, and 75% representing a low, moderate, and high degree of heterogeneity, respectively [27]. The Q-test is a statistical test that

determines whether there is significant heterogeneity among the studies. The significance level for the Q test is set at 0.01 in this review [28]. If significant heterogeneity is detected using the Q-test or I^2 index (> 50%), we will explore potential sources of heterogeneity using subgroup analyses and meta-regression. We will also explore the possible causes (for example, differences in study quality, participants, or outcome assessments) and evaluate the studies in terms of their methodological characteristics to determine whether the degree of heterogeneity can be explained by differences in those characteristics and whether a meta-analysis is appropriate.

Assessment of publication bias

We will create and examine a funnel plot to explore possible small study biases if we can pool more than ten studies in a single meta-analysis. The number of studies that are missing from the funnel plot will be estimated. The effect size after the inputting of these missing studies will be estimated by the trim-and-fill method. The trim and fill method is a simple estimation approach proposed by Duval and Tweedie [29], where they trim off the asymmetric outlying part of the funnel, then use the symmetric remainder to estimate the true center of the funnel, and then replace the trimmed studies and their counterparts around the centre. Other methods to assess the publication bias, including Begg's rank correlation and Egger's weighted regression method test will also be performed [30, 31].

Ethics and dissemination

We registered this systematic review with the Prospero (Systematic review registration: PROSPERO CRD42024500442). Since this review will use published data, ethical approval is waived. The systematic review will focus on donor risk factors in pediatric KT, the results of which will be disseminated by publication in a peer-reviewed journal after completion.

Results

The search and screening for the systematic literature review are anticipated to be finished in August 2025. Data extraction, quality appraisal, and subsequent data synthesis will begin in September 2025. The review is expected to be completed by April 2026, and the study results will be published in 2026.

Discussion

Since the first successful KT in 1954, surgical transplantation techniques have evolved considerably. New approaches to transplant protocols have been revised over the past two decades to overcome organ donor shortage, for example, careful selection of elderly living donors, deceased donors from cardiac deaths and donors with a history of increased infection risk [32]. Concurrently, the management of infants on dialysis has improved, and the number of transplants in smaller sized recipients has increased [33–35]. Immunosuppressive treatment regimens have also evolved, such as the introduction of tacrolimus and mycophenolate mofetil in 1994 which replaced azathioprine and cyclosporine [36]. A contemporary analysis of the factors affecting long-term transplant survival is therefore required. Our emphasis on uniformity in the inclusion criteria and consideration of the evolution of different practices will help to ensure sample representativeness. The design, use of standardized study rating instruments, and adherence to systematic review and meta-analysis guidelines further enhance the study robustness.

In view of the advances in KT, our review will focus on studies from year 2000 onwards. During this time, the systems for allocating deceased donor KT have also evolved considerably [37]. In the UK, a national KAS was first introduced in 1989. HLA matching was introduced in 2006 and utility matching using donor and recipient risk indices was introduced in 2019 [38]. The US implemented a national sharing and donor service areas system with their KAS in 1987. In 2014, a revised US KAS scheme was implemented. Currently, this system employs the Kidney Donor Profile Index (KDPI) to

assess donor kidney quality, with pediatric patients given priority [37, 39]. Australia and New Zealand's allocation system, established in 2008 and revised in 2011, emphasizes national prioritization for well-matched grafts using state-based algorithms for local allocations [40, 41]. European countries have collaborated since 1967 on a registry of kidney transplant candidates to optimize HLA matching, and introduced the Eurotransplant Kidney Allocation System (ETKAS) in 1996. This ETKAS points-scoring system considers factors such as HLA match grade, mismatch probability, waiting time, geographic distance, national balance, medical urgency status, and pediatric age [42]. There are therefore variations in KAS internationally reflecting local priorities, and variations in the way pediatric patients are prioritized [43]. Nonetheless, the donor risk indices which assess donor quality have not shown to be as effective in prognosticating outcomes in pediatric patients [13, 18–20].

We hope a large meta-analysis which combines the results from across the globe will overcome the problem of small sample size in pediatric KT and improve the validity of the analysis. However, there is a need to acknowledge the potential limitations arising from the diverse designs of included studies. Our review will employ subgroup analyses and meta-regression to address high heterogeneity and enhance the overall quality of evidence. Despite potential biases in observational study designs, the use of standardized study rating instruments, compliance with all relevant guidelines for systematic reviews and meta-analyses, and synthesizing evidence from multiple studies, can strengthen the validity of our conclusions. By providing solid and updated reports on donor risk factors in pediatric KT, this review aims to contribute substantially to the refinement of transplantation strategies, policy development, and clinical practice in this critical area of pediatric nephrology. This review findings will be made publicly available and disseminated in article publications and presenting at the conferences either poster or oral presentations.

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Authors' Contributions

CGA, NAM, JJK conceptualized the manuscript. CGA, NHA, IAR conducted the investigation. CGA, NAM, JJK, NHM, IAR developed the methodology. CGA and NAM were selected as the project administration. CGA, NAM, and JJK managed the resources. NAM and JJK were in charge of supervision and validation. CGA was in charge of visualization. CGA wrote the original draft. CGA, NAM, NHM, IAR, and JJK were responsible for review and editing. All authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

Abbreviations

ACROBAT-NRSi: Cochrane risk of bias assessment tool for non-randomized studies of interventions

CMV: Cytomegalovirus

DBD: Donation after brain death

DCD: Donors following circulatory death

ESKD: End-stage kidney disease

ETKAS: Eurotransplant kidney allocation system

HCV: Hepatitis C virus

HLA: Human leukocyte antigen

KAS: Kidney allocation schemes

KDPI: Kidney donor profile index

KT: Kidney transplants

LD: Living donors

MeSH: Medical subject headings

MOOSE: Meta-analysis of observational studies in epidemiology

NOS: Newcastle-Ottawa scale

PRISMA: Preferred reporting items for systematic review and meta-analyses

RCT: Randomized controlled trials

Data Availability

Data sharing is not applicable to this article as no data sets were generated or analysed during the study.

Conflicts of Interest

None declared.

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Supporting information

S1 Checklist. PRISMA checklist.

(DOC)

S1 Table. Proposed search terms.

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