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FACULDADE DE MEDICINA
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Ana Carolina Faria Dias Inácio

Can KDPI score be a predictor of function and survival of kidneys from non-heart beating donors?

Poderá o score KDPI ser um preditor da função e sobrevivência de rins de dadores em paragem cardiocirculatória?

Julho, 2023

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Mestrado Integrado em Medicina

Área: Urologia

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Trabalho efetuado sob a Orientação de:
Prof. Dr. Tiago Vieira Conceição Antunes Lopes

E sob a Coorientação de:
Prof. Dr. João Fernando Alturas da Silva

Trabalho organizado de acordo com as normas da revista:
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UC Dissertação/Projeto (6º Ano) - DECLARAÇÃO DE INTEGRIDADE

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UC Dissertação/Projeto (6º Ano) – DECLARAÇÃO DE REPRODUÇÃO

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DESIGNAÇÃO DA ÁREA DO PROJECTO

MEDICINA CLÍNICA

TÍTULO DISSERTAÇÃO/~~MONOGRAFIA~~ (riscar o que não interessa)

CAN KDPI SCORE BE A PREDICTOR OF FUNCTION AND SURVIVAL OF KIDNEYS FROM NON-HEART BEATING DONORS?

ORIENTADOR

TIAGO VIEIRA CONCEIÇÃO ANTUNES LOPES

COORIENTADOR (se aplicável)

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ASSINALE APENAS UMA DAS OPÇÕES:

É AUTORIZADA A REPRODUÇÃO INTEGRAL DESTE TRABALHO APENAS PARA EFEITOS DE INVESTIGAÇÃO, MEDIANTE DECLARAÇÃO ESCRITA DO INTERESSADO, QUE A TAL SE COMPROMETE.	☐
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Faculdade de Medicina da Universidade do Porto, 30 / 06 / 2023

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Research Article

Can KDPI score be a predictor of function and survival of kidneys from non-heart beating donors?

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Short Title: Can KDPI score be a predictor of function and survival of kidneys from non-heart beating donors?

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Number of Figures: 0

Word count: 1786 words

Keywords: "Kidney Donor Profile Index"; "KDPI"; "renal transplant"; "renal allograft"; "circulatory death donors"

Abstract

Introduction:

Circulatory death donors (CDD) are a growing source of kidney allografts amid current organ demand-supply imbalance. Kidney Donor Profile Index (KDPI) is a well-established score for predicting the risk of graft failure in brain death donors.

The aim of this study was to investigate the value of KDPI to predict graft function following kidney transplantation from CDD donors under extra-corporeal membrane oxygenation (ECMO).

Methods:

We retrospectively reviewed 25 cases of kidney transplants from CDD under ECMO. Electronic health records and national transplantation registry were reviewed, and data was retrieved and analyzed.

Results:

Three (12%) allografts displayed immediate function (IF), 17 (68%) had delayed graft function (DGF) and 5 (20%) showed primary non-function (PNF). No differences could be found between KDPI groups regarding allograft function or survival. Allograft KDPI was significantly higher in the group with PNF when compared with those with DGF (median 66 vs. 35, p=0,015). KDPI did not correlate with estimated glomerular filtration rate (EGFR) at 6 months (r=-0,439, p=0,056).

Conclusions:

In this pilot study, KDPI was significantly higher in the group of patients with PNF. KDPI may be a valuable tool in the evaluation and allocation of kidney allografts from CDD under ECMO.

Introduction

Renal transplantation is the preferred therapy for end-stage renal disease as it enhances survival, quality of life and decreases healthcare costs.[1] Kidney transplant waiting lists have been increasing as population ages and criteria for renal transplantation broadens. For example in the US, the number of active patients on the waiting list has grown from 52,503 in 2009 to 95,052 in 2019.[2] To meet this demand, donor criteria for renal transplantation has also widened. Nevertheless, graft supply remains the rate limiting step. [3]

Brain dead donors (BDD) are the main graft source and classically are divided in standard (SCD) and expanded criteria donors (ECD). ECD include any donor over the age of 60, or a donor over the age of 50 with two of the following items: history of hypertension, serum creatinine greater than or equal to 1.5 mg/dL, or death resulting from a cerebrovascular accident. SCD include donors under the age of 50 not meeting any of the expanded criteria.[4]

Circulatory death donors (CDD) are another significant source of kidney grafts, as they represent the most practical way of expanding the donor supply.[5] For instance, in the United Kingdom, from 2000 to 2009, CDD composed 34% of all deceased donors.[6] Compared to BDD, in addition to the cold ischemia time, CDD also face organ injury determined by warm ischemia time (WIT) elapsing between circulatory death and graft harvesting. WIT is associated with delayed graft function (DGF) and primary non-function (PNF).[7] Ischemic injury can be attenuated by organ preservation strategies, such as extra corporeal membrane oxygenation (ECMO) [8], and DGF and PNF rates appear to be lower in grafts supported by this technique. [9]

Graft survival and long-term outcomes are similar between expanded criteria BDD and CDD. [10] Nevertheless, in BDD, kidney biopsies can be useful to infer graft quality and may eventually lead to organ discard. Recently, OPTN has issued recommendations to obtain kidney histology prior to transplantation in certain scenarios, including expanded criteria donors. [11] Contrariwise, the quality of CDD grafts cannot be easily accessed using this technique as graft retrieval must occur expeditiously in order to minimize ischemia time.

Scoring systems have been proposed to assess transplant quality and eventually forego the need to obtain kidney histology. In addition, biopsy may enhance cold ischemia time and result in excess discard of grafts. [12] Kidney Donor Profile Index (KDPI) has been established as the most effective scoring system to assess the individual risk of a brain-dead donor graft. This score allows for a more judicious and refined risk assessment, than the dichotomous standard vs. expanded criteria donor classification. KDPI includes data on age, height, weight, cause of death, last serum creatinine, history of diabetes, hypertension, HCV-infection, ethnicity, and the discrimination between

donation after brain death versus donation after cardiac death. [13]

Nevertheless, as far as we know, very few studies report on the relationship between KDPI and graft survival in CDD, especially in those supported with ECMO. Therefore, we intend to study if KDPI can predict graft function and/or graft survival in patients transplanted with grafts from CDD under ECMO.

Materials and Methods

We retrospectively reviewed all cases of kidney transplantation with grafts from circulatory death patients under ECMO performed at Centro Hospitalar e Universitário São João between 1st January 2020 and 30th June 2022.

Inclusion criteria were age >18 years, renal transplantation from CDD supported with ECMO. Allografts for which donor information was not accessible due to incomplete clinical registry or refusal to disclose data precluding KDPI calculation were excluded.

Clinical registry and the national transplantation database were assessed and clinical and surgical variables relating to the graft donor were collected, namely: age, height, weight, cause of death, last serum creatinine, history of diabetes, hypertension, HCV-infection, ethnicity. Clinical and surgical variables from the graft recipient were also collected including age, height, weight, renal function at 6 months. Data was included in a database and analyzed. Data confidentiality was assured, and the study was approved by our institution ethics committee.

Principal outcome variable was graft function (estimated glomerular filtration rate - eGFR) at 6 months post-transplant, calculated based on CKD-EPI formula from a whole-blood analysis for creatinine. Secondary outcomes included percentage of delayed graft function and primary non function.

Results

1.Population description

36 CDD kidney transplants from donors under ECMO were performed during the timeframe of our study. Eleven were excluded due to lack of information precluding KDPI calculation. Therefore 25 kidney transplants were included in the study.

Median (IQR) donor age was 46 (20) years and cause of death was cardiac event in all cases. Only one (4%) allograft came from a hepatitis C positive donor, and all were from caucasian donors. Diabetes mellitus afflicted 8% (2 allografts) of allograft donors and arterial hypertension 16% (4 allografts). Mean ± SD last serum creatinine available from the day of the donation was 1,26 ± 0,42.

Median (IQR) KDPI was 45 (42,5).

Median (IQR) recipient age at transplant was 52 (20) years and women represented 40% of allograft recipients. Data regarding donor and allograft recipients can be found in Table1.

Table 1. Baseline characteristics of donors and allograft recipients. n: sample size; IQR: interquartile range; SD: standard deviation.

Donors (n = 25)	
Age (years, median [IQR])	46 [20]
Caucasian n (%)	25 (100%)
Cause of death: cardiac arrest n (%)	25 (100%)
Hepatitis C positive n (%)	1 (4%)
Diabetes *mellitus* n (%)	2 (8%)
Arterial hypertension n (%)	4 (16%)
Pre donation serum creatinine (mg/dL, mean±SD)	1,26 ± 0,42
KDPI (median [IQR])	45 [42,5]
Recipients (n = 25)	
Age (years, median [IQR])	52 [20]
Male n (%)	15 (60%)

2.Allograft function

Three (12%) allografts displayed immediate function (IF), 17 (68%) had delayed graft function (DGF) and 5 (20%) showed primary non-function (PNF). Mean ± SD allograft function at 6 months was 53,96 ± 22,79 mL/min.

3.KDPI and Allograft function

No differences were found between KPDPI groups (<35; 35-85; >85) regarding allograft function or survival. Allograft KDPI was significantly higher in the group with PNF when compared with those with DGF (median 66 vs. 35, p=0,015). The IF group had median KDPI (93). KDPI did not correlate with estimated glomerular filtration rate (EGFR) at 6 months (r=-0,439, p=0,056).

Discussion/Conclusion

Optimization of organ allocation is one of the main challenges of transplant medicine. In the face of organ shortage, CDD are a growing kidney allograft source. Nevertheless, despite facing the added injury of warm ischemia time, these allografts are not amenable to biopsy and histologic characterization due to the urge to reduce ischemia time, in order to improve transplantation success. A tool capable of characterizing graft quality and probable survival could help increasing allograft transplant success, as well as maximize organ availability and optimize graft allocation. The rational behind our study is that KDPI might perform such a role.

KDPI assesses the likelihood of kidney failure in a specific donor compared to the average risk of kidney failure in a kidney donor from the previous year. It was validated in 2014 in the US population for BDD, and has since been used to allocated organs in this country. Furthermore, it has been validated in populations from several European countries, such as Germany and Greece. [14, 15]

The donors in our study had a median age of 40 years. As for receptors, median (IQR) age was 52 (20) years and 40% were women. The epidemiologic characteristics of our receptors and donors matched those described in several cohorts of uncontrolled CDD kidney transplantation. [16, 17]

The series published by Molina et al. in 2018 displaying the results of kidney transplantation from uncontrolled CDD in a Spanish tertiary center found that 88,2 % of donors were man, mean ± SD donor age was 44,5 ± 9,9 years, and mean ± SD pre donation creatinine was 1,3 ± 0,4. Mean ± SD receptor age was 47,9 ± 10,9 and 40,5 % were woman. Furthermore, they described a low HCV infection rate (3,4%), as was found in our study. [18]

In our study only 12 % of grafts displayed immediate function, and the majority (68%) displayed delayed graft function. Our results are in line with published series of CDD transplantation.(17) For example, the previously mentioned series by Molina et al. found 73,4% of delayed graft function and 6,8% of primary non function. [18]

We found allograft KDPI to be significantly higher in the group with PNF when compared with those with DGF, implying KDPI might be able to predict graft function in CDD as it does in BDD. Despite the above referred results and the established role of this index in BDD, in our study no differences in allograft function or survival from CDD could be found. This might be related to limitations in our study's statistical power or to the fact that CDD might have different characteristics and its survival might be related to variables not included in this index.

Our study represents one of the few studies investigating KDPI potential role in predicting allograft survival and function in kidney transplantation from CDD under ECMO. Nevertheless, our conclusions are limited mainly because of the retrospective nature of our cohort, and due to missing

information or variables not consistently reported. Furthermore, the reduced number of included cases limited the statistical power of the obtained results and, therefore its external validity. Further studies with prospective cohorts and larger sample sizes are needed to better characterize KDPI potential to predict graft function in CDD as it does in BDD.

KDPI might predict kidney graft function from CDD under ECMO. Nevertheless, further studies are needed to establish this score's ability to predict graft function and survival from circulatory death donors thereby influencing clinical practice.

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Appendices:

1 – Reporting guidelines

2 – Rules of publication of the selected scientific journal

3 – Proof of acceptance by the Ethics Committee

1 – Reporting guidelines

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	(a) Page 2: (Abstract) "We retrospectively reviewed 25 cases of kidney transplants from CDD under ECMO."
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	(b) Page 2: (Abstract) "We retrospectively reviewed 25 cases of kidney transplants from CDD under ECMO." Page 2 (Abstract): "Three (12%) allografts displayed immediate function (IF), 17 (68%) had delayed graft function (DGF) and 5 (20%) showed primary non-function (PNF). No differences could be found between KPDPI groups regarding allograft function or survival. Allograft KDPI was significantly higher in the group with PNF when compared with those with DGF (median 66 vs. 35, p=0,015). The IF group had an unexpectedly high median KDPI (93). KDPI did not correlate with estimated glomerular filtration rate (EGFR) at 6 months (r=-0,439, p=0,056)."
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 3 (Paragraph 4): "Graft survival and long-term outcomes are similar between expanded criteria BDD and CDD. (10)Nevertheless, in BDD, kidney biopsies can be useful to infer graft quality and may eventually lead to organ

			discard. Recently, OPTN has issued recommendations to obtain kidney histology prior to transplantation in certain scenarios, including expanded criteria donors. (11) Contrariwise, the quality of CDD grafts cannot be easily accessed using this technique as graft retrieval must occur expeditiously in order to minimize ischemia time. Scoring systems have been proposed to assess transplant quality and eventually forego the need to obtain kidney histology. In addition, biopsy may enhance cold ischemia time and result in excess discard of grafts. (12)Kidney Donor Profile Index (KDPI) has been established as the most effective scoring system to assess the individual risk of a brain-dead donor graft. This score allows for a more judicious and refined risk assessment, than the dichotomous standard vs. expanded criteria donor classification. " Page 4 (Paragraph 1): "Nevertheless, as far as we know, very few studies report on the relationship between KDPI and graft survival in CDD, especially in those supported with ECMO."
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 4 (Paragraph 1): "Therefore, we intend to study if KDPI can predict graft function and/or graft survival in patients transplanted with grafts from CDD under ECMO."
Methods			
Study design	4	Present key elements of study design early in the paper	Page 4 (Paragraph 2): "We retrospectively reviewed all cases of kidney transplantation with grafts from circulatory death patients under ECMO performed at Centro Hospitalar e

			Universitário São João between 1st January 2020 and 30th June 2022."
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 4 (Paragraph 2): "We retrospectively reviewed all cases of kidney transplantation with grafts from circulatory death patients under ECMO performed at Centro Hospitalar e Universitário São João between 1st January 2020 and 30th June 2022."
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	(a) Page 4 (Paragraph 3): "Inclusion criteria were age >18 years, renal transplantation from CDD supported with ECMO. Allografts for which donor information was not accessible due to incomplete clinical registry or refusal to disclose data precluding KDPI calculation were excluded."
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	(b) Not Applicable (NA) since it is not a matched study.
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 4 (Paragraph 5): "Principal outcome variable was graft function (estimated glomerular filtration rate - eGFR) at 6 months post-transplant, calculated based on CKD-EPI formula from a whole-blood analysis for creatinine. Secondary outcomes included percentage of delayed graft function and primary non function."
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 4 (Paragraph 4): "Clinical registry and the national transplantation database were assessed and clinical and surgical variables relating to the graft donor were collected, namely: age, height, weight, cause of death, last serum creatinine, history of diabetes, hypertension, HCV-infection, ethnicity.

			Clinical and surgical variables from the graft recipient were also collected including age, height, weight, renal function at 6 months. Data was included in a database and analyzed."
Bias	9	Describe any efforts to address potential sources of bias	Page 4 (Paragraph 3): "Allografts for which donor information was not accessible due to incomplete clinical registry or refusal to disclose data precluding KDPI calculation were excluded."
Study size	10	Explain how the study size was arrived at	Page 4 (Paragraph 2): "We retrospectively reviewed all cases of kidney transplantation with grafts from circulatory death patients under ECMO performed at Centro Hospitalar e Universitário São João between 1st January 2020 and 30th June 2022."
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 4 (Paragraph 4): "Clinical registry and the national transplantation database were assessed and clinical and surgical variables relating to the graft donor were collected, namely: age, height, weight, cause of death, last serum creatinine, history of diabetes, hypertension, HCV-infection, ethnicity. Clinical and surgical variables from the graft recipient were also collected including age, height, weight, renal function at 6 months. Data was included in a database and analyzed."
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	a) Page 4 (Paragraph 5): "Principal outcome variable was graft function (estimated glomerular filtration rate - eGFR) at 6 months post-transplant, calculated based on CKD-EPI formula from a whole-blood analysis for creatinine. Secondary outcomes included percentage of delayed graft function and primary non function."

		(*b*) Describe any methods used to examine subgroups and interactions	(b) Page 4 (Paragraph 5): "Principal outcome variable was graft function (estimated glomerular filtration rate - eGFR) at 6 months post-transplant, calculated based on CKD-EPI formula from a whole-blood analysis for creatinine. Secondary outcomes included percentage of delayed graft function and primary non function."
		(*c*) Explain how missing data were addressed	(c) Page 4 (Paragraph 3): "Allografts for which donor information was not accessible due to incomplete clinical registry or refusal to disclose data precluding KDPI calculation were excluded."
		(*d*) If applicable, explain how loss to follow-up was addressed	(d) Not Applicable
		(*e*) Describe any sensitivity analyses	(e) Not Applicable
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	(a) Page 4 (Paragraph 6): "36 CDD kidney transplants from donors under ECMO were performed during the timeframe of our study. Eleven were excluded due to lack of information precluding KDPI calculation. Therefore 25 kidney transplants were included in the study."
		(b) Give reasons for non-participation at each stage	(b) Page 4 (Paragraph 6): "Eleven were excluded due to lack of information precluding KDPI calculation."
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	(a) Page 4 (Paragraph 7): "Median (IQR) donor age was 46 (20) years and cause of death was cardiac event in all cases. Only one (4%) allograft came from a hepatitis C positive donor, and all were from caucasian donors. Diabetes

			mellitus afflicted 8% (2 allografts) of allograft donors and arterial hypertension 16% (4 allografts). Mean ± SD last serum creatinine available from the day of the donation was 1,26 ± 0,42. Median (IQR) KDPI was 45 (42,5). Median (IQR) recipient age at transplant was 52 (20) years and women represented 40% of allograft recipients. Data regarding donor and allograft recipients can be found in Table 1."
		(b) Indicate number of participants with missing data for each variable of interest	(b) Page 4 (Paragraph 6): "Eleven were excluded due to lack of information precluding KDPI calculation."
		(c) Summarise follow-up time (eg, average and total amount)	(c) Not Applicable
Outcome data	15*	Report numbers of outcome events or summary measures over time	Page 5 (Paragraph 3): "Three (12%) allografts displayed immediate function (IF), 17 (68%) had delayed graft function (DGF) and 5 (20%) showed primary non-function (PNF). Mean ± SD allograft function at 6 months was 53,96 ± 22,79 mL/min." Page 5 (Paragraph 4): "No differences were found between KPDPI groups (<35; 35-85; >85) regarding allograft function or survival. Allograft KDPI was significantly higher in the group with PNF when compared with those with DGF (median 66 vs. 35, p=0,015). The IF group had median KDPI (93). KDPI did not correlate with estimated glomerular filtration rate (EGFR) at 6 months (r=-0,439, p=0,056)."
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	(a) Page 4 (Paragraph 7): "Median (IQR) donor age was 46 (20) years and cause of death was cardiac event in all

			cases. Only one (4%) allograft came from a hepatitis C positive donor, and all were from caucasian donors. Diabetes mellitus afflicted 8% (2 allografts) of allograft donors and arterial hypertension 16% (4 allografts). Mean ± SD last serum creatinine available from the day of the donation was 1,26 ± 0,42. Median (IQR) KDPI was 45 (42,5). Median (IQR) recipient age at transplant was 52 (20) years and women represented 40% of allograft recipients. Data regarding donor and allograft recipients can be found in Table1.“
		(*b*) Report category boundaries when continuous variables were categorized	(b) Page 5 (Paragraph 3): “No differences were found between KPDPI groups (<35; 35-85; >85) regarding allograft function or survival.”
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	(c) Not Applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 5 (Paragraph 3): “No differences were found between KPDPI groups (<35; 35-85; >85) regarding allograft function or survival. Allograft KDPI was significantly higher in the group with PNF when compared with those with DGF (median 66 vs. 35, p=0,015).”
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 6 (Paragraph 4): “In our study only 12% of grafts displayed immediate function, and the majority (68%) displayed delayed graft function. Our results are in line with published series of CDD transplantation.(17) For

			example, the previously mentioned series by Molina et al. found 73,4% of delayed graft function and 6,8% of primary non function. [18] We found allograft KDPI to be significantly higher in the group with PNF when compared with those with DGF, implying KDPI might be able to predict graft function in CDD as it does in BDD. Despite the above referred results and the established role of this index in BDD, in our study no differences in allograft function or survival from CDD could be found."
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 6 (Paragraph 5): "This might be related to limitations in our study's statistical power or to the fact that CDD might have different characteristics and its survival might be related to variables not included in this index." Page 6 (Paragraph 6): "Nevertheless, our conclusions are limited mainly because of the retrospective nature of our cohort, and due to missing information or variables not consistently reported. Furthermore, the reduced number of included cases limited the statistical power of the obtained results and, therefore its external validity."
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 7 (Paragraph 1): "KDPI might predict kidney graft function from CDD under ECMO. Nevertheless, further studies are needed to establish this score's ability to predict graft function and survival from circulatory death donors thereby influencing clinical

			practice."
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 7 (Paragraph 1); "Furthermore, the reduced number of included cases limited the statistical power of the obtained results and, therefore its external validity."
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	(c) Not Applicable

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

2 – Rules of publication of the selected scientific journal

(available at: https://karger.com/uin/pages/guidelines)

Urologia Internationalis

Guidelines

CONTENTS

About the Journal

Aims and Scope

Concise but fully substantiated international reports of clinically oriented research into the science and current management of urogenital disorders form the nucleus of original as well as basic research papers. These are supplemented by up-to-date reviews by international experts on the state of the art of key topics of clinical urological practice. Essential topics receiving regular coverage include the introduction of new techniques and instrumentation as well as the evaluation of new functional tests and diagnostic methods. Special attention is given to advances in new surgical techniques and clinical oncology. The regular publication of selected case reports represents the great variation in urological disease and illustrates treatment solutions in singular cases.

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3 – Proof of acceptance by the Ethics Committee

Parecer da Comissão de Ética do
Centro Hospitalar Universitário de São João / Faculdade de Medicina da Universidade do Porto

Título do Projeto: Can KDPI score be a predictor of function and survival of kidneys from non-heart beating donors?

Nome do Investigador Principal: Dr. João Pedro Figueiredo Oliveira

Onde decorre o Estudo: Nos Serviços de Urologia e Nefrologia do CHUSJ. Apresentou declaração do Prof. Doutor Carlos Silva Martins e do Prof. Doutor Manuel Pestana.

Objetivos do Estudo:
Estudar se o 'Kidney Donor Profile Index' (KDPI) consegue predizer a função ou sobrevida do aloenxerto renal proveniente de dadores em morte cardíaca submetidos a ECMO.

Conceção e Pertinência do estudo:
Este estudo observacional retrospetivo pretende rever todos os casos de aloenxerto renal proveniente de dadores em morte cardíaca submetidos a ECMO, de modo a permitir o acesso à evidência mais recente no cálculo do risco de falência do aloenxerto.
Estão definidos os critérios de inclusão e os dados a ser recolhidos.

Beneficio/risco: Não aplicável

Confidencialidade dos dados:
Os dados serão codificados.
Apresentou um pedido de reutilização de registos clínicos para Investigação e Desenvolvimento ao RAI, e a 'avaliação sobre o impacto da proteção de dados' para o EPD.

Respeito pela liberdade e autonomia do sujeito de ensaio:
Prevê utilizar o modelo de CI do CHUSJ e disponibilizar uma informação aos participantes, mas não entregou nenhum destes documentos.

***Curriculum* do investigador**: Adequado à investigação.

Data previsível da conclusão do estudo: dezembro de 2023

Conclusão: Proponho um parecer favorável à realização do estudo, após o esclarecimento da questão assinalada a itálico.

Porto, 16 de dezembro de 2022

O Relator da CE, Doutor Pedro Brito

Pedro Brito