

Family refusal to donate a cornea for transplantation: associated factors and trends

Recusa familiar para doação de córneas para transplante: fatores associados e tendência
Negativa familiar para donación de córneas para trasplante: factores asociados y tendencia

Isabelle Cristina Nogueira da Silva¹  <https://orcid.org/0000-0003-0445-2971>

Rafael Rodrigo da Silva Pimentel¹  <https://orcid.org/0000-0002-9461-1472>

Edvaldo Leal de Moraes¹  <https://orcid.org/0000-0002-6320-3812>

Marcelo José dos Santos¹  <https://orcid.org/0000-0001-5123-8797>

How to cite:

Silva IC, Pimentel RR, Moraes EL, Santos MJ. Family refusal to donate a cornea for transplantation: associated factors and trends. Acta Paul Enferm. 2024;37:eAPE001471.

DOI

<http://dx.doi.org/10.37689/acta-ape/2024A000001471>



Keywords

Tissue and organ procurement; Tissue donors; Corneal transplantation; Refusal to participate; Family

Descritores

Obtenção de tecidos e órgãos; Doadores de tecidos; Transplante de córnea; Recusa de participação; Família

Descriptores

Obtención de tejidos y órganos; Donantes de tejidos; Trasplante de córnea; Negativa a participar; Familia

Submitted

June 19, 2023

Accepted

August 30, 2023

Corresponding author

Isabelle Cristina Nogueira da Silva
Email: isa.silva.nogueira22@gmail.com

Associate Editor (Peer review process):

Bartira de Aguiar Roza
(<https://orcid.org/0000-0002-6445-6846>)
Escola Paulista de Enfermagem, Universidade Federal de São Paulo; São Paulo, SP, Brazil

Abstract

Objective: To analyze family refusals to donate a cornea for transplantation in an Organ Procurement Organization.

Methods: This was a quantitative cross-sectional study on corneal donation refusals from potential brain-dead donors. The data source was based on the Terms of Authorization for Donation of Organs and Tissues signed from January 2001 to December 2020 in an Organ Procurement Organization. Data were collected, tabulated, and analyzed in a descriptive and inferential manner. The present study was approved by the Research Ethics Committee.

Results: Of the 2,447 Terms of Authorization for Donation of Organs and Tissues signed in the above period, 620 (25.34%) of them refused to donate a cornea. Regarding the time trend of corneal donation refusals, the period 2001-2009 was the only one that showed significance, when the 0-11 and 12-19 age groups showed a decreasing trend and that of 60 years or older showed an increasing trend. In the period 2001-2020, the age groups of 20-40, 41-59, and 60 years or older had lower rates of refusal to donate a cornea (48%, 59%, and 73%, respectively).

Conclusion: The age group is associated with refusal because older individuals had the highest refusal rates.

Resumo

Objetivo: Analisar a recusa familiar de doação de córnea para transplante em uma Organização de Procura de Órgãos.

Métodos: Estudo quantitativo do tipo transversal sobre as recusas de córnea de doadores em situação de morte encefálica. A fonte de dados foi constituída pelos Termos de Autorização de Doação de Órgãos e Tecidos firmados entre janeiro de 2001 a dezembro de 2020 em uma Organização de Procura de Órgãos. Os dados foram coletados, tabulados e analisados de forma descritiva e inferencial. O presente estudo foi aprovado pelo Comitê de Ética em Pesquisa.

Resultados: Dos 2.447 Termos de Autorização de Doação de Órgãos e Tecidos firmados no período, 620 (25.34%) recusaram a doação de córneas. Com relação à tendência temporal de recusas de doação de córneas, o único período que apresentou significância foi de 2001 a 2009, quando as faixas etárias de zero a 11 anos e 12 a 19 anos demonstraram tendência decrescente, e a faixa etária maior ou igual a 60 anos, mostrou-se crescente. No período total de 2001 a 2020, as faixas etárias dos 20 a 40 anos, 41 a 59 anos e maior ou igual a 60 anos apresentaram, 48%, 59% e 73%, respectivamente, menores chances de recusa da doação de córneas.

Conclusão: A faixa etária apresentou associação com a recusa, tendo em vista que os indivíduos de maior idade apresentaram maiores índices.

¹Escola de Enfermagem, Universidade de São Paulo; São Paulo, SP, Brazil.

Conflicts of interest: the authors declare there is no conflict of interest.

Resumen

Objetivo: Analizar la negativa familiar de donación de córneas para trasplante en una Organización de Búsqueda de Órganos.

Métodos: Estudio cuantitativo tipo transversal sobre la negativa de córnea de donantes en situación de muerte encefálica. La fuente de datos estuvo compuesta por los Términos de Autorización de Donación de Órganos y Tejidos firmados entre enero de 2001 y diciembre de 2020 en una Organización de Búsqueda de Órganos. Se recopiló los datos, luego se tabularon y se analizaron de forma descriptiva e inferencial. El presente estudio fue aprobado por el Comité de Ética en Investigación.

Resultados: De los 2447 Términos de Autorización de Donación de Órganos y Tejidos firmados en el período, 620 (25,34 %) negaron la donación de córneas. Con relación a la tendencia temporal de negativas de donación de córneas, el único período que presentó significación fue de 2001 a 2009, cuando los grupos de edad de 0 a 11 años y de 12 a 19 años demostraron una tendencia decreciente, y el grupo de edad mayor o igual a 60 años se mostró creciente. En el período total de 2001 a 2020, los grupos de edad de 20 a 40 años, de 41 a 59 años y mayor o igual a 60 años presentaron un 48 %, un 59 % y un 73 %, respectivamente, menor probabilidad de negativa de donación de córneas.

Conclusión: El grupo de edad presentó relación con la negativa, considerando que los individuos de mayor edad presentan mayores índices.

Introduction

The cornea is a transparent tissue in the anterior portion of the eyeball, allowing the entry of light and still exerting a focus-related function.⁽¹⁾ In many cases, corneal diseases can lead to a decrease in visual acuity, causing reversible blindness in 4-5% of cases.⁽²⁾

Corneal transplantation is an important alternative that should assist in the partial or total recovery of vision in cases of more severe pathology; some of the major corneal pathologies, such as Fuchs' dystrophy, keratoconus, primary corneal edema, and sequelae of infectious keratitis, require transplantation as a form of treatment.^(2,3)

Tissues, including the cornea, can be donated after the diagnosis of both brain death and death due to cardiopulmonary arrest. Brain death consists of the complete and irreversible stoppage of all structures of the human brain; in Brazil, the diagnosis is made based on two clinical exams and a complementary exam, which must be performed by two different doctors and with an interval of hours, according to the patient's age.⁽⁴⁾ Death by cardiorespiratory arrest is the cessation of the heart's work of pumping oxygenated blood into the brain and other structures of the human body.⁽⁵⁾

Corneal donation can be performed in both cases, but obtaining it is often associated with cardiac arrest; in this case, only the tissues for donation (including the cornea) can be removed up to 6 h after death.⁽⁶⁾ However, donation after brain death is feasible; the lower rate of refusal to donate corneas observed in these cases contributes to meeting the demands of the population.⁽⁷⁾

In recent years, the Brazilian scenario of corneal donations for transplantation has advanced. In the period 2001-2016, increases in the number of corneal transplants (2.4 times) and effectiveness in meeting the demand for corneal transplants (50.7%) occurred.⁽⁸⁾

However, the population's need for corneal transplantation remains greater than the supply, despite the observed improvements; family refusal to donate a cornea for transplantation is a possible cause.⁽⁸⁾ One study indicated that this lag scenario is repeated at various locations worldwide.⁽³⁾

In March 2020, the World Health Organization declared the Covid-19 pandemic as the result of the action of the Sars-Cov-2 virus, a highly communicable and infectious virus. This greatly affected the rates of donation and transplantation of organs and tissues in various ways, mainly in the suspension of elective surgeries.^(9,10) Given the cases with the possibility of donation, a slight decrease was still observed in family refusals to donate organs and tissues for transplantation in Brazil. The refusal rate found in 2020 (37%) was lower than those observed in 2018 (43%) and 2019 (40%).⁽¹¹⁾

According to the Brazilian Association of Organ Transplantation (BAOT), 21,161 people were on the waiting list to receive corneal transplants in Brazil until December 2022.⁽¹¹⁾ In Brazil, a law (9,434; 02/04/1997) regulates the donation of organs and tissues for transplantation, requiring family authorization to donate.⁽¹²⁾ The consent or not of the family is obtained in an interview, which is conducted by a trained professional with the donor's family representative, in which the possibility

of donation is discussed and the organs and tissues that can be removed are decided.⁽¹³⁾

Given the importance of family authorization for the process to continue, establishing public policies is necessary to make the population aware of the importance of donations and the safety of the process, so that all doubts of family members of potential donors are resolved, thus reducing the refusals and serving the population who is waiting for a transplant.

It is believed that the lack of information to potential donor families about the process and the importance of the donation are some obstacles to corneal donation for transplantation, in addition to legal, logistical, or religious issues.⁽²⁾ The education and kinship degree of the family members interviewed, as well as the shift in which the interview is carried out, also influence the consolidation of donations.⁽¹⁾

Therefore, analyzing family refusals to donate a cornea for transplantation in an Organ Procurement Organization was the aim of this study.

Methods

This was a quantitative cross-sectional analytical study of an exploratory and retrospective character on the refusals of family members of potential corneal donors in a situation of brain death.

The scenario for this research was the territory where an Organ Procurement Organization (OPO) encompasses 96 hospitals in the State of São Paulo.

The analysis material consisted of all Terms of Authorization for Donation of Organs and Tissues signed by donor family members from January 2001 to December 2020.

The data of interest were collected and tabulated in a Microsoft Excel® spreadsheet. The study variables related to refusal of corneal donation were as follows: year (2001-2020), donor age (0-11, 12-19, 20-40, 41-59, and 60 years or older), gender (female and male), cause of death (cerebrovascular accident, traumatic brain injury, anoxic encephalopathy after cardiac arrest, external causes, etc.), type of hospital (public and private), and refusal to donate cornea.

The final version of the database was transferred from Microsoft Excel® to the Stata (v. 15.0) software, in which the analyses were performed. Chi-square tests were sequentially applied to test hypotheses of association between acceptance or refusal of donation and sociodemographic, clinical, and administration-type variables.

The temporal trend analysis was performed using the Prais-Winsten-type generalized linear regression, in which the beta 1 coefficients (β_1) (with first-order temporal autocorrelation correction) and the respective 95% confidence intervals were estimated. Refusals to donate corneas in the general population and subgroups (male gender, public administration, and the age groups of 0-11, 12-19, 20-40, 41-59, and 60 years or older) were considered as dependent variables. The estimated coefficients were used to calculate the percentage trend or change evidenced by the Annual Percent Change (APC) parameter and the respective 95% confidence intervals. The APC values were calculated based on the formula demonstrated by Antunes and Cardoso.⁽¹⁴⁾

In addition, the relative variation coefficients in the periods of interest were calculated. For this, the difference between the percentages of refusal in the final and initial years of the analyzed period was divided by the percentage in the initial year. To interpret the results, the increasing (mean annual percent change, APC, significantly positive; $p < 0.05$), decreasing (significantly negative change rate; $p < 0.05$), and stationary (accepting the null hypothesis that there is no significant difference between the variation and zero; $p > 0.05$) tendencies were considered.⁽¹⁴⁾

A multiple logistic regression-type multivariate analysis was performed to estimate the chances of refusing to donate organs and/or tissues. Initially, the crude odds ratios (OR) and the respective 95% confidence intervals were estimated for the following subgroups: male gender, public administration, and the age ranges of 12-19, 20-40, 41-59, and 60 years or older. The 5% significance level was adopted in all analyses.

This study is part of a larger research project (Analysis of donations of organs and tissues for trans-

plantation that occurred in an Organ Procurement Organization in the State of São Paulo in the period 2001-2020) which was approved by the institutional Research Ethics Committee according to opinion (4,737,972) registered in *Plataforma Brasil* (Certificate of Presentation of Ethical Appreciation: 30589920.9.0000.0068), respecting the norms of the National Health Council.

Results

In the period studied, 2,447 Terms of Authorization for Donation of Organs and Tissues were signed; 1,827 (74.66% 74.7) of them were for donation and 620 (25.34% 25.3) for refusal of corneal donation. Regarding the characteristics of individuals who refused to donate corneas, the age range was significant ($p<0.001$), and the highest number of refusals was observed in the 41-59 age group (Table 1).

Table 1. Characterization of corneal donations and refusals that occurred in the period 2001-2020 (n=2,447)

Variables	Refusals n(%)	Donations n(%)	p values [†]
Sex			
Female	276 (44.52)	733 (40.12)	0.055
Male	344 (55.48)	1094 (59.88)	
Age range (years)			
0-11	39 (6.29)	53 (2.90)	<0.001
12-19	72 (11.61)	131 (7.17)	
20-40	199 (32.10)	519 (28.41)	
41-59	246 (39.68)	812 (44.44)	
60 years or older	64 (10.32)	312 (17.08)	
Diagnosis			
Brain stroke	308 (49.68)	946 (51.78)	0.158
Traumatic Brain Injury	185 (29.84)	570 (31.20)	
Anoxia	46 (7.42)	112 (6.13)	
External causes	45 (7.26)	131 (7.17)	
Others*	36 (5.81)	68 (3.72)	
Administration types			
Public administration	349 (56.29)	1012 (55.39)	0.697
Private administration	271 (43.71)	815 (44.61)	

Chi-square test. *Others: Brain abscess; cerebral, diffuse cerebral, cerebral (due to diabetic ketoacidosis and/or exogenous intoxication) edemas; hepatic encephalopathy, viral encephalitis, hydrocephalus, arteriovenous malformation (AVM), meningococcal meningitis; bacterial, meningococcal, and pneumococcal meningitis; Deandy-Walker syndrome + Hydrocephalus; brain tumor, and pituitary tumor.

In the period 2001-2009, the temporal trend of corneal donation refusals for the age groups of 0-11 (APC: -0.99; CI: -1.09; -0.27; $p=0.040$) and 12-19 years (APC: -0.99; CI: -1.08; -0.82; $p=0.008$) decreased. In the age group of 60 years or older, the

temporal trend of refusals showed to be increasing (APC: 140.25; CI: 3.78; 424.67; $p=0.011$) (Table 2). In the second period (2010-2020), no variable showed a significant trend. The other variables (male gender; public administration; 20-40 and 41-59 years old; general population) showed a stationary temporal trend in the analyzed periods (Table 2).

In the period 2001-2009, the age groups of 41-59 ($p=0.002$) and 60 years or older ($p<0.001$) had lower chances of refusing cornea donation (66.0 and 81.0%, respectively) compared to the age group of 0-11 years (Table 3). In the period 2010-2020, the age groups of 20-40 ($p=0.040$), 41-59 ($p=0.008$), and 60 years or older ($p<0.001$) showed lower chances of refusal (47.0, 55.0, and 69.0%, respectively), when compared to the age group of 0-11 years (Table 3). In the period 2001-2020, the age groups of 20-40 ($p=0.004$), 41-59 ($p<0.001$), and 60 years or older ($p<0.001$) had lower chances of refusing cornea donation (48.0, 59.0, and 73.0%, respectively). In this period, the diagnoses of brain stroke ($p=0.025$) and traumatic brain injury ($p=0.028$) showed lower chances of refusal (39.0 and 23.0%, respectively), compared to other diagnoses (Table 3).

Discussion

With basis on the above results, the specific family refusal to donate cornea was analyzed in an Organ Procurement Organization in the State of São Paulo. After analysis, the age group was associated with refusal, whereas older individuals had higher refusal indices.

A study carried out in Australia (2006) also indicated an association between the potential donor's age and specific refusal to donate a cornea, and increasing age was positively related to the chances of donating a cornea.⁽¹⁵⁾ However, the positive relationship of this study is opposed by our results. A Brazilian study, which was carried out in the period 2007-2008 at a University Hospital in the State of Paraná, did not observe a significant association between donor age and effective donation.⁽¹⁶⁾ Thus, the variation observed in the results on this theme

Table 2. Time trend of the percentages of specific refusal to donate cornea by characterization variables in the periods 2001-2009 and 2010-2020

Variables	2001 n (%)	2009 n (%)	APC [‡] (IC95%)	Δ%	p-values	2010 n (%)	2020 n (%)	APC [‡] (IC95%)	Δ%	p-values
Male sex	31 (73.81)	10 (43.48)	-0.99 (-1.01; 7.91)	-40.09	0.113	50 (52.08)	17 (60.71)	-0.52 (-0.96; 5.16)	16.57	0.527
Public sector	23 (54.76)	10 (43.48)	34.48 (6.24; 931.15)	-20.59	0.172	52 (54.17)	19 (67.86)	0.42 (-0.83; 11.02)	25.27	0.707
0-11 years	5 (11.90)	1 (4.35)	-0.99 (-1.09; -0.27)	-63.44	0.040	3 (3.13)	0 (0)	-0.43 (-0.92; 2.98)	-	0.520
12-19 years	8 (19.05)	2 (8.70)	-0.99 (-1.08; -0.82)	-54.33	0.008	8 (8.33)	4 (14.29)	0.20 (-1.69; 1.86)	71.54	0.915
20-40 years	17 (40.48)	6 (26.09)	-0.16 (-0.99; 12.20)	-35.54	0.951	28 (29.17)	11 (39.29)	3.47 (-0.93; 29.41)	34.69	0.439
41-59 years	11 (26.19)	8 (34.78)	50.28 (-0.99; 501.18)	32.79	0.521	47 (48.96)	10 (35.71)	1.48 (-0.94; 11.20)	-27.06	0.603
60 years or older	1 (2.38)	6 (26.09)	140.25 (3.78; 424.67)	996.21	0.011	10 (10.42)	3 (10.71)	-0.76 (-0.98; 4.01)	2.78	0.312
General population	70.00	13.29	-0.99 (-1.11; 0.28)	-81.01	0.057	57.49	18.54	-0.86 (-0.99; 18.05)	-67.75	0.387

[‡]Annual Percent Change calculated with basis on the β value of the Prais-Winsten regression

Table 3. Association between specific refusal of cornea donation and sociodemographic characteristics considering the raw Odds Ratio (OR)

Variables	2001-2009		2010-2020		2001-2020	
	OR (95%CI)	p-values	OR (95%CI)	p-values	OR (95%CI)	p-values
Sex						
Female	1	-	1	-	1	-
Male	0.89 (0.63; 1.25)	0.511	0.80 (0.64; 1.02)	0.058	0.83 (0.69; 1.03)	0.055
Age ranges (years)						
0-11	1	-	1	-	1	-
12-19	0.56 (0.25; 1.27)	0.172	0.86 (0.44; 1.66)	0.661	0.74 (0.45; 1.23)	0.256
20-40	0.50 (0.25; 1.01)	0.053	0.53 (0.29; 0.97)	0.040	0.52 (0.33; 0.81)	0.004
41-59	0.34 (0.17; 0.67)	0.002	0.45 (0.25; 0.81)	0.008	0.41 (0.26; 0.63)	<0.001
≥60	0.19 (0.08; 0.46)	<0.001	0.31 (0.16; 0.60)	<0.001	0.27 (0.17; 0.45)	<0.001
Diagnosis						
Brain stroke	0.55 (0.25; 1.20)	0.135	0.64 (0.38; 1.06)	0.088	0.61 (0.40; 0.93)	0.025
Traumatic Brain Injury	0.67 (0.29; 1.53)	0.347	0.60 (0.36; 1.01)	0.057	0.61 (0.39; 0.94)	0.028
Anoxia	1.01 (0.38; 2.72)	0.971	0.70 (0.37; 1.32)	0.280	0.77 (0.45; 1.31)	0.348
External causes	0.44 (0.18; 1.03)	0.059	1.72 (0.77; 3.84)	0.180	0.64 (0.38; 1.09)	0.108
Others*	1	-	1	-	1	-
Administration types						
Public administration	1.13 (0.80; 1.59)	0.461	0.98 (0.78; 1.23)	0.895	1.03 (0.86; 1.24)	0.697
Private administration	1	-	1	-	1	-

*Others: brain abscess; cerebral and diffuse cerebral edemas and cerebral edemas due to diabetic ketoacidosis and exogenous intoxication; hepatic encephalopathy, viral encephalitis, hydrocephalus, arteriovenous malformation (AVM), meningoencephalitis; bacterial, meningococcal, and pneumococcal meningitis; Deandy-Walker syndrome + Hydrocephalus, and brain and pituitary tumors.

suggests an additional study to better understand this aspect.

As the donor's age does not affect the procedure's success, this result is also relevant if the endothelial cell count was adequate. Then, even the donation of the cornea from older individuals (the age group that most refused donation) would significantly

contribute to supplying the eye bank, favoring future transplants.^(16,17)

Analyzing the temporal trend in the period 2001-2009, a decreasing trend was identified in the age groups of 0-11 and 12-19 years (and an increasing trend in the age group of 60 years or older) indicating an increase in refusals simultaneously with

the increase in age. In the period 2010-2020, no variable showed a significant trend. In a study carried out at an Organ Procurement Organization in the city of São Paulo in the period 2001-2016, it was observed that corneal donation remained stationary for more than a decade, whereas donation of other tissues presented lower rates.⁽¹⁸⁾

The present study began in 2001 when the highest rate of family refusal of corneal donation was observed. On 09/06/2001, the Ministry of Health created the National Program for Implementation of Eye Banks (Ordinance 1559) within the scope of the National Transplant System. Through this Ordinance, the Program objectives were established. They must offer implantation conditions for the Eye Banks, in addition to other actions, enabling a wide collection of cornea for transplantation (with the necessary technical and safety conditions), thus increasing the number of transplants and reducing waiting lists.⁽¹⁹⁾

It was possible to observe that the creation of the National Program for Implementation of Eye Banks enabled significant changes, as a drop was noted in the refusal rates in the following years. In addition, the *Cornea-Fila Zero* Campaign was launched in São Paulo in 2003 by Mayor Marta Suplicy to provide more information to the population about corneal donation for transplantation, thus contributing to the fall in refusal rates.^(20, 21)

The year 2009 was relevant because the lowest rate of refusal occurred in it within the entire study period. In that year, Ordinance 2600 (10/21/2009) approved the Technical Regulation of the National Transplantation System. However, the drop in refusals is probably not associated with this approval, as it occurred in the second half of the year and a significant change in the index for that year would not be possible.⁽²²⁾ Thus, we presume that the drop is a reflection of the pattern observed in previous years.

The implementation of the Technical Regulation of the National Transplant System was not enough to generate positive results (relative to corneal donations in 2010); they completely diverged from the repetitive pattern observed in previous years, with the second highest rate of refusals in the period.

Also in 2010, the Transplant Center (that coordinates the State Transplant System of the São Paulo State Health Department) changed the Donation Authorization Term, which started to be used in family interviews. With the use of this new Term, a 17.2% increase was observed in authorizations for corneal donation. Thus, the evidence found in the literature was not sufficient to explain the reason for the increase in refusal rates in that year, indicating the need for further studies to explore the characteristics of this period.⁽²³⁾

Concerning 2020 (when the Covid-19 pandemic was declared), the non-increase in the refusal rate was an important observation; in fact, this index has also decreased throughout Brazil.⁽¹¹⁾ One issue that may be related to this was the death of an important Brazilian artist due to brain death at the end of 2019: the donation of his organs and tissues was authorized by his family members, generating a lot of publicity on the subject on social media, thus bringing this subject for discussion in many families and social settings.⁽²⁴⁾

Regarding the association between corneal donation refusals and sociodemographic characteristics, the age groups showed a certain kind of percentage pattern in all analyzed periods. In all cases, older individuals had higher percentages of chance of refusing donation when compared to the 0-11 age group.

It is interesting to emphasize that the findings of the present study confirm those of previous studies that indicate specific refusal of corneal donation when donation of other organs and tissues was accepted.⁽¹⁵⁾ A study conducted in the East explains how donation-related terminology can influence effective donation.⁽²⁵⁾ In the case of cornea donation, the use of terms such as “donation and/or eye bank” should be avoided, replacing them with “donation and/or ocular tissue bank” or specifically cornea donation. Not only the stigma associated with the removal of eyes for donation (and all its meanings in society) should be considered but also make the interpretation and expression of family members clearer in the choice of tissues to be donated.⁽²⁵⁾

Another study indicates that other aspects related to the population, in addition to those presented

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