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ORIGINAL PAPER

Impact of SARS-CoV-2 Pandemic on Ocular Tissue Donation in a Teaching Hospital

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ABSTRACT

Objectives: To analyze the impact of the severe acute respiratory syndrome coronavirus (SARS-CoV-2) pandemic on ocular tissue donations, assessing lost opportunities for potential donors due to the suspension of collections and changes in eligibility criteria, as well as hospital eligibility rates of donors and causes of non-donation. **Methods:** Data from patients who died in cardiopulmonary arrest in a Brazilian university hospital in 2020 were analyzed. The number of donations made, the number of deaths potentially eligible for donation, and the causes of non-donation were compared during the three periods of 2020: period 1, pre-pandemic (January 1 to March 18, 2020), period 2, with suspension of donations in cardiorespiratory arrest (March 19 to September 19, 2020), and period 3, of collections with epidemiological screening for SARS-CoV-2 and reduction of the age range of donors **less than** 65 years old (September 20 to December 31 2020). **Results:** There were 710 circulatory deaths in 2020. The hospital eligibility rate was 5.7% among 140 deaths in the pre-pandemic period 1, 11.9% among 395 patients during the suspension of uptake in pandemic period 2, and 3.4% among 175 patients during age group restrictions and coronavirus disease 2019 (COVID-19) screening (p:0.004). Forty-seven patients who died in period 2 represented a loss of donation opportunities due to the suspension of collections, and 13 (7.6%) of the 175 patients in period 3 were ineligible due to the reduction in age group. Due to pandemic restrictions, eighty-one percent of the 75 eligible patients without clinical contraindications had limited tissue donation offers. Only one patient was considered ineligible for donation due to clinical-epidemiological screening for SARS-CoV-2. Serious infections were the leading cause of non-donation in 50.7, 48.1, and 47.4% of deaths in the three periods (p:0.615). **Conclusion:** The SARS-CoV-2 pandemic significantly affected the procurement of ocular tissues for transplants due to the restrictive measures implemented for safety reasons, leading to the loss of donation opportunities for 81% of families. Age restrictions significantly reduced potential donor eligibility rates. Serious infections were the leading cause of non-donation of ocular tissue, but it did not increase significantly in this study during the pandemic, in the period studied.

Descriptors: Tissue Transplantation; Tissue Donors; SARS-CoV-2; COVID-19; Tissue and Organ Procurement.

Impacto da Pandemia da SARS-CoV-2 nas Doações de Tecidos Oculares para Transplantes em Hospital Universitário

RESUMO

Objetivos: Analisar o impacto da pandemia da síndrome respiratória aguda grave do coronavírus 2 (SARS-CoV-2) nas doações de tecidos oculares quanto às perdas de oportunidade de potenciais doadores devido à suspensão das captações e às mudanças nos critérios de elegibilidade, nas taxas de elegibilidade hospitalar de doadores e causas de não doação. **Métodos:** Foram analisados dados de pacientes falecidos em parada cardiorrespiratória (PCR) em um hospital universitário brasileiro em 2020. Compararam-se o número de doações efetivadas, o número de óbitos potencialmente elegíveis para doação e as causas de não doação nos três períodos de 2020: período 1, pré-pandemia (1 de janeiro a 18 de março de 2020), período 2, com suspensão de doações em PCR (19 de março a 19 de setembro de 2020), e período 3, de captações com triagem epidemiológica para SARS-CoV-2 e redução da faixa etária de doadores até 65 anos (20 de setembro a 31 de dezembro de 2020). **Resultados:** Houve 710 óbitos por morte circulatória em 2020. A taxa de elegibilidade hospitalar foi de 5,7% em 140 óbitos no período 1, 11,9% de 395 pacientes durante a suspensão da captação no período 2 e 3,4% de 175 pacientes durante as restrições da faixa etária e triagem para doença do coronavírus 2019 (COVID-19) (p = 0,004). Os 47 pacientes falecidos no período 2 representaram perda de oportunidade de doação devido à suspensão das captações e 13 (7,6%) dos 175 pacientes no período 3 não foram elegíveis devido à redução da faixa etária. Dentre os elegíveis sem contraindicação clínica, 81%

dos 75 pacientes tiveram limitação na oferta de doação devido às restrições da pandemia. Apenas um paciente foi considerado inelegível para doação devido à triagem clínico-epidemiológica para SARS-CoV-2. As infecções graves foram a principal causa de não doação em 50,7, 48,1 e 47,4% dos óbitos nos três períodos (p = 0,615). **Conclusão:** A pandemia de SARS-CoV-2 afetou significativamente a captação de tecidos oculares para transplantes devido às medidas restritivas implementadas por motivos de segurança, resultando na perda de oportunidade de doação para 81% das famílias. As taxas de elegibilidade de potenciais doadores foram reduzidas significativamente pela restrição de faixa etária. As infecções graves foram a principal causa de não doação de tecidos oculares, porém, neste estudo, não houve aumento significativo durante o período pandêmico estudado.

Descritores: Transplante de Tecidos; Doadores de Tecidos; SARS-CoV-2; COVID-19; Obtenção de Tecidos e Órgãos.

INTRODUCTION

Diseases that affect the cornea account for around 4 to 5% of cases of reversible blindness worldwide. Conditions such as bullous keratopathy, keratoconus, trachoma, Fuchs dystrophy and infectious keratitis, when not treated adequately, in addition to the natural history of the disease, can cause significant biopsychosocial damage to individuals[1].

Corneal transplantation is an effective therapy for treating these conditions and, in some cases, the only widely accepted treatment capable of promoting corneal transparency and vision restoration.

Although the cornea is the most transplanted tissue in the world and presents the best results, the shortage of donors is also a global reality[1-3].

The shortage of organs and tissues for transplantation purposes was greatly aggravated by the coronavirus pandemic, initially characterized by the outbreak of cases of atypical pneumonia in Wuhan, China, in December 2019. Later, it was called severe acute respiratory syndrome coronavirus 2 (SARS—CoV-2), marking the year 2020 in Brazil and around the world[4].

The growing number of cases affecting 114 countries on all continents led the World Health Organization (WHO) to declare a pandemic on March 11, 2020[2,4,5]. The disease, initially characterized by signs and symptoms such as fever, cough, myalgia and fatigue, can progress with a systemic inflammatory response and multiple organ failure caused by the new coronavirus, it was named COVID-19, from the English coronavirus disease 2019[2,5].

Organ and tissue transplant programs were directly affected in Brazil and around the world with the reduction in the rate of effective donors per million population (PMP) and the suspension of the harvesting of ocular tissues in patients who died in the stopped heart modality, increasing the number of patients on waiting lists[6-8].

Minas Gerais (MG), a state with 21,412 inhabitants, is Brazil's second most populous state, representing approximately 9.9% of the country's population and the fourth state in the absolute number of ocular tissue transplants. However, when evaluating the number of PMP transplants, MG falls to 17th position[7-9].

As determined by the Ministry of Health (Ministério da Saúde-MS), the General Coordination of the National Transplant System (Sistema Nacional de Transplantes-SNT) published in March 2020, recommendations to contain the transmission of the coronavirus (SARS-CoV-2) for healthcare professionals, patients on the waiting list and transplant recipients. These recommendations aimed to be implemented urgently - Technical Note No. 25/2020 determining the "Technical criteria for clinical screening of coronavirus (SARS, MERS, SARS-CoV-2)"[10].

As a result of these measures, the collection of ocular tissues for transplants was reduced, it became restricted to multiple organ donors, and elective corneal transplants were suspended[10].

Given the heterogeneity of the epidemiological situation between Brazilian states, the Ministry of Health recommended that the resumption of donation processes and elective transplants should consider the epidemiological situation of SARS-CoV-2 transmission at the local and regional level[10].

In MG, the period from March 19 to September 19, 2020, was marked by the suspension of the capture of ocular tissues from patients who died in the stopped heart modality, considered the phase of increased risk for the transmission of SARS-CoV-2 in recipients and health professionals involved in the harvesting and transplantation process[9-12].

The resumption of collections in the state took place from September 20, 2020, subject to the new criteria for validation of deceased donors of ocular tissues defined by the Ministry of Health and recommendations for clinical screening focusing on the epidemiological history for SARS-CoV-2 guided by the Ocular Tissue Bank of reference[12].

In this context, the Ocular Tissue Bank of reference for this institution adhered to the recommendations contained in the Contingency Plan of the State of Minas Gerais, *Minas Consciente*, and advised that collections be suspended in regions classified by the plan as "red wave"[9,12].

Several studies have analyzed the impact of the SARS-CoV-2 pandemic on organ and tissue transplants. Still, few reports have been published evaluating the effects of the processes of harvesting and donating ocular tissues in patients who died of cardiorespiratory arrest (CRA) and on the rates of eligibility of potential tissue donors[13-16].

This study analyzed the pandemic's impact on ocular tissue harvesting in donors who died in CRA, considering the losses of opportunities for potential donations during the suspension of ocular tissue harvesting and the impact of the new donor eligibility criteria. , with exclusion based on epidemiological screening and reduction of the age range established by the Eye Bank of reference for this hospital in MG.

METHODS

The present is a study with a quantitative approach of a descriptive nature that was used as a basis for the database built by the Intra-hospital Commission for Donation of Organs and Tissues for Transplantation (Comissão Intra-hospitalar de Doação de Órgãos e Tecidos para Transplante-CIHDOTT) of a university hospital located in the city of Belo Horizonte, MG. The period established for data analysis covers the months of January to December 2020.

Forms I and III were used as analysis instruments, corresponding to Annex 19 of Annex I of Consolidation Ordinance No. 04 of September 28, 2017[17].

Form I, called "Daily Activity Report of the Intra-hospital Commission for Donation of Organs and Tissues for Transplantation – CIHDOTT – the possibility of tissue donation, after the occurrence of death (post-CRA)", is a hospital record instrument that contains all hospital deaths by CRA, including data on patients who died in the institution, such as name, age, cause of death, sector, whether or not tissue was donated and the cause of non-donation classified as defined in Annex 19 of Annex I of the Ordinance Consolidation No. 04 of September 28, 2017.

For this study, all cases with no clinical contraindication for ocular tissue donation in which the donation opportunity was not offered to the relatives of the deceased patient were classified as a cause of non-donation, receiving code 023, due to suspension of collections, as a health containment measure during the SARS-CoV-2 pandemic. These cases were considered lost opportunities for potential donations due to the pandemic.

Form III, called "Monthly Report on the Activities of the Intra-hospital Commission for Donation of Organs and Tissues for Transplants – CIHDOTT", consists of an instrument summarizing the monthly statistics of hospital deaths and information related to the collection processes sent to the State Center of Transplants – MG Transplantes.

The analyzed database comprises the consolidated Form I and III from January to December 2020. The period from March 19 to September 19, 2020, was marked by the suspension of the collection of ocular tissues from patients who died in cardiac arrest and considered a phase of increased risk for the transmission of SARS-CoV-2 in recipients and healthcare professionals involved in the capture and implantation process[10,12].

The new criteria defined by this reference service for the eligibility of potential donors during the resumption of ocular tissue collection from deceased donors by CRA from September 20 to December 2020 are characterized by "Patient without clinical, physical and (according to Collegiate Board Resolution 55 and screening for COVID-19), aged less then 65 years and after family authorization"[17,18].

The period from January 1 to March 18, 2020, was called pre-pandemic period 1, the period from March 19 to September 19, 2020, was called period 2, of suspension of ocular tissue harvesting in patients who died in CRA, and period 3 considered collection with epidemiological screening restrictions for SARS-CoV-2 and reduction in the age range of donors.

The eligibility rate of potential donors corresponds to the percentage of patients who do not meet the defined exclusion criteria concerning the total number of deaths due to CRA in the period [17,18].

The data contained in Forms I and III, from January to December 2020, were consolidated into a spreadsheet in the Microsoft Excel® program of Microsoft Office Plus Professional 2016 and analyzed with the statistical analysis tools of Microsoft Excel® and the Epi program InfoTM 7 from the Centers for Disease Control and Prevention (CDC).

Descriptive statistics analyses and comparative analysis of proportions were carried out for eligibility rates between periods, applying the chi-square test or two-tailed Fisher's exact test for event values ≤ 5, defining a p-value ≤ 0.05 to interpret statistical significance.

The study followed the standards recommended in Resolution No. 466 of December 12, 2012, of the National Health Council (CNS), which refers to research involving human beings, and the project was approved by the Research Ethics Committee with CAAE no. 56517521.5. 0000.5149.

RESULTS

During the studied period, there were 710 circulatory deaths, 140 in pre-pandemic period 1, 395 in period 2, during the suspension of collections, and 175 in period 3, when collections resumed with age group restrictions and epidemiological screening to exclude the risk of transmission of SARS-CoV-2.

A higher frequency of deaths was observed in males and the age group of 60 to 79 years in the three periods, with no statistical differences (p > 0.05) in the distribution between the pre-pandemic phase and the pandemic period (Table 1).

Table 1. Distribution by gender and age group of deaths, 2020.

	Pre-pandemic		Suspension of harvesting in CRA			Screening for COVID-19 and reducing the age group < 65 years		
	n	%	n	%	p-value	n	%	p-value
Gender								
Female	66	47	193	49	0,726	85	47	0,887
Male	74	53	202	51		89	51	
Not informed	0		0			1		
Age range (years)								
≤ 2	20	14	42	11	0,245	27	16	0,836
>2 ≤ 18	3	2	14	4	0,26	5	3	0,465
>18 ≤ 40	6	4	28	7	0,242	4	2	0,352
> 40 ≤ 60	37	26	105	27	0,971	51	30	0,604
> 60 ≤ 79	64	46	165	42	0,417	73	42	0,494
> 79	10	7	41	10	0,262	15	9	0,742
Total	140		395			175		

Source: Prepared by the authors. p-value calculated in comparison with the pre-pandemic phase.

Seventy-two patients died related to COVID-19, and serious infections were the leading cause of donor exclusion in the three periods compared (Table 2). There was no significant difference in the proportion of severe infections as a contraindication for donation from the pre-pandemic period to the pandemic phase studied (p = 0.615).

The second most frequent cause of potential donor exclusion was the age group criterion, corresponding to 22.9, 21 and 32% in the respective pre-pandemic periods, suspension of collections and collection with restricted criteria. The reduction in the donation age range to 65 years in period 3 caused a significant increase in the proportion of patients excluded from donation due to the new exclusion range (p = 0.004).

Throughout the year, there were eight donations of ocular tissue and three family refusals. Among the two refusals in the pre-pandemic period, one was justified by the donor being against living donation and the other by the indecision of family members. Refusal during the pandemic was related to family members' desire for the integrity of the patient's body.

Regarding eligibility, eight (5,7%) patients were identified in the pre-pandemic phase, 47 (11,9%) patients during the suspension and 6 (3,4%) patients in the collection period with restrictions who were eligible for donation. There was a significant reduction in the eligibility rate based on the exclusion criteria for period 3 (p = 0.004).

Table 2. Outcome of evaluation and donation of ocular tissues, 2020.

	Pre-pandemic		Suspension of harvesting in CRA		Screening for COVID-19 and reducing the age group < 65 years	
Reasons for non-donation	n	%	n	%	n	%
Opposite donor while alive	1	0,7	0	0,0	0	0,0
Undecided family members	1	0,7	0	0,0	0	0,0
They want the complete body	0	0,0	0	0,0	1	0,6
HIV	3	2,1	4	1,0	1	0,6
Hepatitis B	0	0,0	2	0,5	3	1,8
Hepatitis C	1	0,7	4	1,0	1	0,6
Serious infection	69	49,3	190	48,1	81	47,4
Neoplasia	6	4,3	23	5,8	15	8,8
No diagnosis	1	0,7	3	0,8	0	0,0
Out of age range	32	22,9	83	21,0	56*	32,0
Other clinical reasons	20	14,3	39	9,9	10	5,8
Degree of kinship does not allow donation	0	0,0	0	0,0	1	0,6
Structural deficiency	2	1,4	0	0,0	1	0,6
Suspension of COVID-19 harvesting or screening**	NSA	0,0	47	11,9	1**	8,2
Subtotal	136	97,1	395	100,0	171	97,7
Eligible Patients	8	5,7	47	11,9	6	3,4
Donation carried out	4	66,7	NA	NA	4	80,0
Family refusal	2	33,0	NA	NA	1	20,0
Total	140	19,7	395	55,6	175	24,6

Source: Elaborated by the authors. NA = not applicable. *13 eligible patients were excluded from donation due to the reduction in the age range for donation from 80 to 65 years. **1 patient was excluded by epidemiological screening for SARS-CoV-2 in period 3.

Among the 14 patients excluded as possible donors according to the additional exclusion criteria of period 3, 13 (92.8%) were aged between 65 and 80 years and one (7.2%) was excluded due to respiratory failure associated with the mediastinal and pulmonary tumor mass when applying the epidemiological screening criteria for risk of transmission of SARS-CoV-2 of Technical Note nº 80/2020[10].

DISCUSSION

This study demonstrated that the suspension of ocular tissue harvesting in patients who died of circulatory death during the period of suspension of elective keratoplasties excluded 77% of the total 61 potential ocular tissue donor patients in the studied hospital.

Additionally, the restriction on collection by donation age group from 65 years of age onwards when collections resumed, which occurred from September 2020 together with epidemiological screening, excluded another 14 patients who would have been eligible outside the pandemic scenario, totaling the exclusion 81% of patients eligible for donation due to the restrictions imposed in the first year of the pandemic.

Considering the 72% donation rate observed during the recruitment periods and excluding 21% of escapes due to structural deficiencies, at least 27 donors were no longer recruited during the suspension period. Collection gaps, identified as patients eligible as ocular tissue donors whose families were not consulted regarding the donation, constitute a structural problem that still affects ocular tissue donations across the country, as can be estimated from the number of deaths in circulatory death and the number of ocular tissue donations[11].

The scarcity of literature regarding the deficit in ocular tissue uptake in death due to a stopped heart in hospital institutions during the periods established in this study makes it impossible to discuss the data found. However, the impact generated by the suspension followed by restrictions on the return of harvesting is perceived by the growing number of patients on the list and the increased waiting time for transplantation[19].

The reduction in the age range for ocular tissue harvesting is included in the attributions established in the SNT's technical regulations for state centers, considering cost-effectiveness analyses, waiting lists, transplant quality, and the possibility of allocating grafts to other states[17].

In the context of the pandemic, this restriction had the severe effect of significantly reducing the donor eligibility rate in a critical period, which probably contributed to the increase in the waiting list for cornea transplants in the state, which reached 39.6% due to reduced availability of corneas for transplants[9].

Moriyama et al.[6] reported the impact of COVID-19 in the same period, increasing the waiting list by 27.6% in the state of São Paulo and 43.7% in Brazil.

The adopted epidemiological screening criteria for COVID-19, which are very sensitive and have low specificity, did not significantly impact the exclusion of potential donors[10,12].

The suspension of the capture of ocular tissues in cases of circulatory death led to the depletion of cornea stocks, even for emergency transplants in some eye banks, and the restrictive measure related to the mechanism of death, not adopted in other countries for COVID-19 control, was questioned [13].

Another much-debated aspect was the delay in updating Brazilian health standards to keep up with scientific knowledge on the transmission of SARS-CoV-2 in eye transplants[13]. Brazilian health standards remained more restrictive than in the United States and some European countries until the update in December 2023, when there was no more extended reference to the mandatory reverse transcription-polymerase chain reaction (RT-PCR) SARS-CoV-2 test in a patient who died in CRA, and the absolute exclusion criterion for a donor became infection confirmed less than 10 days ago and not 28 days ago, as previously. The impact on the risk-benefit of this time to update the standards for the thousands of patients on the list has yet to be evaluated[19-22].

In 2023, with the end of the pandemic alert declared by the WHO, we continue to have a waiting list in the country twice as long as in 2019. With an influx of patients more significant than the number of transplants performed, the disproportion between ocular tissue supply and demand is increasing[19,23].

Reducing this problem is a challenge for the organization of our donation and transplantation system, which begins with the ability to notify and evaluate possible deceased donors through CIHDOTTs[17].

The main limitation of this study is the evaluation of data from only one hospital. It presents the additional limitation of the institution being a reference for onco-hematology care, presenting lower eligibility rates than those expected in general hospitals[24].

CONCLUSION

The SARS-CoV-2 pandemic had a significant impact on the harvesting of ocular tissues for transplants both in the hospital and in MG, mainly due to the restriction, in Brazil, of harvesting related to the mechanism of circulatory death and the reduction in the age range for harvesting, which resulted in the loss of donation opportunities for 81% of the families served.

Historically lower than in other general hospitals due to the profile of patients served, potential donor eligibility rates were further reduced due to age restrictions, contributing to an even smaller donor pool.

Serious infections were the leading cause of non-donation of ocular tissue; however, in this study, despite the high mortality from COVID-19 during this period, there was no significant increase in the proportion of serious infections as a cause of potential donor exclusion.

CONFLICT OF INTEREST

Nothing to declare.

AUTHOR'S CONTRIBUTION

Substantive scientific and intellectual contributions to the study: Magalhães ACM, Carvalho EAP; **Conception and design:** Magalhães ACM, Carvalho EAP**; Data analysis and interpretation:** Magalhães ACM, Carvalho EAP**; Article writing:** Magalhães ACM, Carvalho EAP**; Critical revision:** Boteon JE, Silva LCS, Faria TBC, Cruz RCSC, Nascimento SZ; **Final approval:** Boteon JE, Silva LCS, Faria TBC, Cruz RCSC, Nascimento SZ.

DATA AVAILABILITY STATEMENT

All dataset were generated or analyzed in the current study.

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