

Critical analysis of the different data sources on corneal transplantation in Brazil

Análise crítica das diferentes fontes de dados sobre transplante de córnea no Brasil

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ABSTRACT

Corneal diseases account for about 4 to 5% of reversible blindness in the world. Corneal transplantation is the most transplanted tissue in the world and the only widely accepted treatment to promote corneal transparency and restore vision. Monitoring was incorporated into the field of Public Health, with the objective of systematically monitoring teams' performance and production data, through the creation of norms, periodic evaluation inspections and monitoring of quality indicators. The critical analyzes of the results aim to point out flaws and risks involved in the process, and to undertake actions capable of modifying the negative findings, in order to improve the quality of the services provided to the population. In Brazil, there are different sources of data on corneal transplants and ocular tissue banks. In this review, the accuracy of the data and the reliability of the information disclosed by the National Transplant System by the Brazilian Organ Transplant Association and the National Sanitary Surveillance Agency on the situation of corneal transplantation in Brazil were evaluated in order to guide governments, public health managers and researchers.

Keywords: Health profile; Cornea; Corneal transplantation; Directed tissue donation, Eye banks

RESUMO

As doenças da córnea são responsáveis por cerca de 4 a 5% da cegueira reversível no mundo. O transplante de córnea é o tecido mais transplantado em todo o mundo e o único tratamento amplamente aceito para promover a transparência corneana e restaurar a visão. O monitoramento incorporou-se ao campo da Saúde Pública, com o objetivo de acompanhar sistematicamente a atuação das equipes e os dados de produção, por meio da criação de normas, inspeções de avaliação periódicas e acompanhamento dos indicadores de qualidade. As análises críticas dos resultados objetivam apontar falhas e riscos envolvidos no processo, e empreender ações capazes de modificar os achados negativos, a fim de aprimorar a qualidade dos serviços prestados à população. No Brasil, existem diferentes fontes de dados sobre transplantes de córnea e bancos de tecidos oculares. Nesta revisão, foi avaliada a precisão dos dados e a confiabilidade das informações divulgadas pelo Sistema Nacional de Transplantes, pela Associação Brasileira de Transplante de Órgãos e pela Agência Nacional de Vigilância Sanitária sobre a situação do transplante de córnea no Brasil, a fim de nortear governos, gestores em saúde pública e pesquisadores.

Descritores: Perfil de saúde; Córnea; Transplante de córnea; Doação dirigida de tecido; Bancos de olhos

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INTRODUCTION

Corneal diseases account for about 4% to 5% of reversible blindness in the world.⁽¹⁻²⁾ Diseases such as bullous keratopathy, keratoconus, trachoma, Fuchs's dystrophy and infectious keratitis, if not treated properly or due to the natural history of the disease, can cause important biopsychosocial damages to patients.⁽¹⁻⁵⁾

Corneal transplant is the most transplanted tissue in the world, and the only treatment widely accepted to promote corneal transparency and restore sight.⁽⁶⁾ A global study warned that the demand for corneal transplants has increased and is not being met due to the scarcity of corneal donors worldwide.⁽⁷⁾

Monitoring was incorporated into the field of Public Health aiming at systematically monitor the teams' performance and production data through the creation of standards, periodic evaluation inspections, and monitoring of quality indicators. The critical analyzes of the results aim to point out flaws and risks involved in the process, and to undertake actions capable of modifying the negative findings, in order to improve the quality of the services provided to the population.⁽⁸⁾

In Brazil, Associação Brasileira de Transplante de Órgãos (ABTO), a non-profit organization founded in 1987, aims to promote the development of activities related to organ and tissue transplants, congregate professionals and transplant teams, stimulate the creation of donation centers, organ and tissue banks, and receiver identification services, leveraging research and collaboration in the dissemination of knowledge about organ and tissue transplants in Brazil.⁽⁹⁾

Founded in 1997, Sistema Nacional de Transplantes (SNT) is responsible to control and monitor the entire process of donation, collection, storage and distribution of tissues in Brazil. The responsibilities of SNT include financing management, donation stimulation, recruitment logistics, accreditation of surgical teams and transplantation centers, and drafting of ordinances to regulate the process.⁽¹⁰⁾

Created in 1999, Agência Nacional de Vigilância Sanitária (ANVISA) is a regulatory agency linked to the Ministry of Health responsible for sanitary control of all products and services subject to sanitary surveillance, including the health services and Ocular Tissue Banks (BTO).⁽⁸⁾

Thus, considering that in Brazil there are different sources of data on corneal and BTO transplant, the present review aimed to evaluate the accuracy of the data and the reliability of the information disclosed by SNT, ABTO and ANVISA on the situation of corneal transplant in Brazil, in order to guide governments, public health managers and researchers.

METHODS

This is a narrative and analytical review study focusing on the critical analysis of the data disclosed on corneal transplants and BTO in Brazil from January 2002 to December 2016, published by Sistema Nacional de Transplantes, Associação Brasileira de Transplante de Órgãos and Agência Nacional de Vigilância Sanitária.

Data research was carried out from October to December 2017 based on the Brazilian legislation on organ and tissue transplants, on scientific articles published on the subject and indexed in the electronic database PUBMED, and on the annual data available on the digital platform of the SNT⁽¹⁰⁾, the RBT

published by ABTO⁽⁹⁾ and on the RADPBTO published by ANVISA.⁽⁸⁾

Scientific articles with the following descriptors were considered: health profile, cornea, corneal transplant, eye banks, directed tissue donation, and demand for organs and tissues. It should be noted that this review did not have any financial assistance, and that the authors declare no conflicts of interest.

Brazilian Legislation

The National Organ and Tissue Transplantation Policy⁽¹¹⁾ is based on laws to guarantee free donation, beneficence towards receivers, and non-maleficence towards donors. Brazilian legislation determines that tissues and organs are made available for transplant after the family consent of the deceased donor through the signing of a donation term, in compliance with the provisions of the Transplant Law.⁽¹²⁾ Therefore, the donation in the country is not presumed, but rather consented, since the family has the power to assent or deny the donation, regardless of the will of the donor in life.^(11,12)

The waiting list for transplants is unique in each state of Brazil, and the treatment is in order of registration, considering the emergency criteria (eyeball perforation, corneal ulcer unresponsive to treatment, descemetocoele, primary graft failure and bilateral corneal opacity in patients younger seven years old) as priorities.^(11,12)

In 2001, the Brazilian Ministry of Health established the National Program for the Implementation of Ocular Tissue Banks aiming to generate the necessary conditions for the implantation of thirty BTOs, with the objective of increasing the collection of corneas, increasing the number of cornea of performed, and shorten the waiting time in the country.⁽¹²⁾

In Brazil, the BTO must comply with the legal requirements for authorization and installation, which includes determinations such as: be in a hospital with a minimum physical area, be approved by the local health surveillance, as well as by Municipal and State Health Secretariats, justify the need for a BTO in the region, and get SNT approval.⁽¹²⁾

After installation, the BTO becomes responsible for capturing corneas and ocular tissues, evaluating the quality and feasibility for transplantation, preservation and storage of the donated cornea. Each BTO has a specific evaluation protocol of donor button, performed systematically on all donated tissues. After identification and serologic release, the cornea is analyzed in all its structures and, only after this evaluation, the physician will grade the tissue quality and determine its usefulness for penetrant, lamellar or tectonic corneal transplant.^(11,12)

ANVISA, in order to guarantee the quality and safety of the tissues that are supplied for therapeutic use in Brazil, published the Resolution of the Board of Directors (RDC) providing good practices in human tissues required in the operation of BTOs.⁽¹³⁾ This RDC determines that BTOs must have a quality management system encompassing initial and periodic employee training, a program of preventive and corrective maintenance of equipment and instruments, validation and control of critical processes, and management of documents. The RDC also establishes the obligation of BTO to send their production data regularly to ANVISA, otherwise it constitutes a sanitary infraction subjecting the banks to the penalties provided for in Law No. 6,437.⁽¹⁴⁾

Data Release

The US is a worldwide reference in corneal transplants. In 2016, 136,318 corneas of 69,049 donors were collected, and

82,994 keratoplasty were performed in the country. Annually, the Eye Bank Association of America (EBAA) publishes a detailed statistical report on the entire process involving donation, collection, storage, distribution and transplant of corneas in the country. This report aims at identifying and sharing the best practices, recognizing possible flaws in the process, and tracking development and global trends in keratoplasty.⁽¹⁵⁾

Thus, in the US, the scientific community, public health managers, ophthalmic societies, population and transplant teams have access to detailed donor demographic data, donor cornea quality, tissue disposal reasons, type and indications of cornea transplant, number and location of BOT. All of this information is released for the purpose of identifying probable errors, minimizing difficulties, and suggesting changes to improve the system governing corneal transplants in the country.⁽¹⁵⁾

In Brazil, ABTO annually releases the Brazilian Transplant Registry (RBT) since 1997 in Portuguese and English, with national and regional data on all types of transplants performed in the country, including corneal transplants. The RBT aims to outline the national activity profile of organ and tissue transplants, and encourage donation in the country.⁽⁹⁾ Since 2001, SNT publishes national data on corneal transplants on its digital platform.⁽¹⁰⁾

Data common to the annual RBT and SNT reports are: (1) the general number of organ and cornea transplants in Brazil, in the regions and states; (2) cornea transplant rate per million of population (PMP) in Brazil, in the regions and states; (3) number of potential donors, effective donors and non-donors of organs and tissues; (4) effective donor rate of PMP organs and tissues; (5) number of family interviews and family refusal to donation; (6) total number of patients waiting for organ and corneal transplants in Brazil, in the regions and states; and (7) number of corneal transplant teams registered in Brazil.^(9,10)

However, despite describing the same variables, the data annually released by SNT and ABTO are scarce, incomplete and divergent in values in many aspects, which hinders the homogeneity of the research, which discusses failures and improvements in the Brazilian transplant system. It is important to emphasize that there are still data available only by ABTO⁽⁹⁾ (estimated annual need for corneal transplant, number and causes of death and reasons for non-donation of organs and tissues in Brazil) and only by SNT⁽¹⁰⁾ (registered transplant centers and the amount spent on corneal transplants and other processes involving donation, such as dissemination actions, collection of exams, tissue processing, follow-up, and post-surgery interurrences).

In addition, SNT and ABTO do not report demographic data on cornea receivers (age, time in the waiting list, indication and type of transplant performed), which are essential for comparison with international research and to put Brazil in the world context of cornea transplants.

ANVISA, in turn, collects production data regularly from Brazilian BTOs and, through the Blood, Tissues, Cells and Organs Management Department, has annually published the RADPBTO since 2009, in order to inform society, health managers, and federal, state and municipal governments about the production data, and to evaluate the BTO quality indicators in operation in Brazil. RADPBTO includes information on the number and geographical location of BTOs in operation in the country, number of corneas and globes donated, collected, preserved, discarded, available for cornea transplant and for other purposes, and causes of corneal discard in Brazilian BTOs. In addition, the report annually calculates corneal preservation efficacy, corneal discard coefficient, and corneal transplant efficacy in Brazil.⁽⁸⁾

However, RADPBTO does not disclose the number of potential cornea donors, demographic data of cornea donors (age, gender, causa mortis), time elapsed between death and cornea collection, time between collection and preservation of the cornea in a specific medium, preservation solution used in the BTO, reasons for the improper quality of the tissue, agents causing contamination of the donor cornea, causes of contraindication to the donation of identified corneas, and causes of refusal of the cornea provided for transplant by the transplant team.

The lack of disclosure of these data makes it difficult to understand the real needs of each state and region of Brazil. Therefore, Brazilian literature⁽¹⁶⁻²³⁾ is scarce in national data analyzes and suggestions for progress in strategic and logistic planning in relation to donation, collection, storage and distribution of corneas, which would optimize the situation of corneal transplant in Brazil.

Therefore, as there are different sources of information on corneal transplants and BTO functioning in Brazil, this review criticizes the data released by SNT, ABTO and ANVISA, which are not standardized and discussed properly, in order to propose solutions and changes to the cornea transplant scenario in the country. This lack of uniformity in the availability of national data can lead to mistaken analyzes and adoption of incorrect decisions in public health, increasing the social, cultural and economic heterogeneity among the regions of Brazil, and causing losses and delays in the cornea transplant system in Brazil.

CONCLUSION

The data released annually by the SNT, ABTO and ANVISA are mandatory for monitoring and evaluation of the situation of corneal transplant in Brazil. However, there are still divergent, incomplete and insufficient data to give a correct analysis on the difficulties and progress related to corneal transplants performed and ocular tissue banks operating in Brazil.

Therefore, it is important to establish the standardization in the dissemination of national data on corneal transplants and ocular tissue banks in Brazil among the responsible regulatory bodies, in order to correctly guide governments, public health managers, ophthalmological societies and researchers in the discussion of local difficulties and proposing specific solutions. This would help improve the Brazilian transplant system in order to make more effective the capacity to supply the population demand for corneal transplants and improve the quality of life of the patients, their families and the society in general.

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