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REVIEW ARTICLE

Eye bank procedures: donor selection criteria

Procedimentos em banco de olhos: critério de seleção do doador

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ABSTRACT | Eye banks use sterile procedures to manipulate the eye, antiseptic measures for ocular surface decontamination, and rigorous criteria for donor selection to minimize the possibility of disease transmission due to corneal grafting. Donor selection focuses on analysis of medical records and specific post-mortem serological tests. To guide and standardize procedures, eye bank associations and government agencies provide lists of absolute and relative contraindications for use of the tissue based on donor health history. These lists are guardians of the Hippocratic principle "*primum non nocere*." However, each transplantation carries risk of transmission of potentially harmful agents to the recipient. The aim of the procedures is not to eliminate risk, but limit it to a reasonable level. The balance between safety and corneal availability needs to be maintained by exercising prudence without disproportionate rigor.

Keywords: Eye banks/standards; Corneal transplantation; Donor selection; Tissue and organ harvesting

RESUMO | Os bancos de olhos utilizam procedimentos estéreis na manipulação dos olhos, medidas antissépticas para a descontaminação da superfície ocular e critério rigoroso de seleção do doador. Essa seleção é feita por meio do prontuário médico e de testes sorológicos específicos *post mortem*. Para orientá-la e uniformizá-la, as associações de bancos de olhos e órgãos governamentais fornecem listas de contraindicações absolutas e relativas de uso do tecido, baseadas nas condições prévias de saúde do doador. Essas listas são as guardiãs do princípio de Hipócrates "*primum non nocere*" e, como tal, são conservadoras. Entretanto, cada transplante traz o risco de transmissão de agentes potencialmente nocivos ao receptor. O objetivo não é eliminar esse risco, mas limitá-lo a um nível razoável. Existe um equilíbrio entre a segurança e a disponibilidade de córneas. A sabedoria está em manter esse equilíbrio, exercendo a prudência sem rigor exagerado.

Descritores: Bancos de olhos/normas; Transplante de córnea; Seleção do doador; Coleta de tecidos e órgãos

INTRODUCTION

Corneal transplantation allows vision recovery at low cost in people whose eyes present disorders of corneal transparency or curvature. The distinguishing feature of this procedure compared to other types of transplantations is that candidates for surgery are usually not blind. They may be unfit for clerical work or driving, but not for routine activities of life. However, if the graft fails, blindness and ocular pain become real possibilities. The selection process that accomplishes this goal constitutes the quality control of the donor tissue[1]. It focuses on three issues: innocuity, transparency, and vitality. This review pertains only to aspects of donor selection related to graft innocuity, i.e., prevention of donor-to-host disease transmission.

Minimizing contamination of eyeballs

Care of the graft begins at the time of eye removal. Immediately before the procedure, ocular surface and conjunctival sacs are washed with 10 ml of physiologic salt solution[2]. Next, eyelids are painted with antiseptic solution, and the operative area is delimitated with a fenestrated sterile field. The eye bank technician, wearing sterile apron, cap, mask, and gloves, removes the eyes and places them in sterile, screw-capped flasks lined with gauze soaked in saline. These containers are known as moist chambers due to their ability to provide a humid environment to the eyeballs. The moist chambers are transferred to the eye bank in thermal protective boxes filled with ice at 2 to 6°C.

The above precautions, bacterial contamination of donated-eye surfaces have been reported to occur at rates of 12%-100%[2-5]. Fungal contamination rates range from 0.02% to 11.5%[2,6-8]. These numbers are important

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when considering a possible association between contaminated corneoscleral buttons and endophthalmitis[9-11]. Incidence of endophthalmitis in corneal transplantation is 0.02%[12]. To minimize risk of germ transmission to the recipient, donor eyeballs undergo a decontamination process, which varies from simple washing with saline[6,13,14] to complete immersion in an antiseptic[7,8] or antibiotic solution [4,14]. Among antiseptics, PVPI has the distinctive property of acting on bacteria, fungi, and viruses. When used at a concentration of 5 mg/ml (0.5%) for two minutes, it reduces eye contamination by half without causing corneal damage. Larger concentrations and longer immersion periods increase chances of toxicity to corneal fibroblasts without strengthening the antimicrobial effect[15]. In our eye bank, the preferred method is dipping the eye in 0.03% ciprofloxacin commercial solution for 10 minutes. Even a 5-minute immersion time results in bacterial decontamination rates of 86% to 100% with a confidence level of 95%[16].

After treatment, the corneas are removed from the eye and transferred to a preservation medium. Both procedures are done inside a laminar-flow cabinet. The main advantage of working with the whole eye is the ability to soak it in an antibiotic or antiseptic solution without risk of endothelial toxicity. Modern preservation media use gentamicin and streptomycinforantibacterial protection.

The next step involves donor selection. This procedure relies upon analysis of donor medical records and post-mortem serological testing for AIDS, hepatitis B, and hepatitis C. The corneas are discarded if one or more of these tests are not feasible.

Analysis of medical records

The health history of the cornea donor contained in medical records is a suitable means for eliminating potentially harmful donations. Death certificate reports and data collected from family members and acquaintances are acceptable alternatives in the absence of a better option. Donations are rejected when no information about the donor is available.

Diseases transmitted via corneal transplantation include bacterial and fungal infections[17], rabies[18,19], hepatitis B[20], and retinoblastoma[21]. Transmission of Creutzfeldt-Jakob disease by this route is conjectural[22-24]. Although the AIDS virus has been retrieved from tears[25] and corneoscleral buttons[26], no reports of its transmission via corneal grafting are found. The literature describes inadvertent transplantation of two pairs of corneas from HIV carriers into healthy patients, with no seroconversion in any of the recipients during a 440-day follow-up[27]. In another report, transplantations performed with tissue from two asymptomatic HIV carriers had the following outcome: two kidney recipients developed symptoms of AIDS and seroconversion at 12 and 56 days after transplantation, respectively, and three corneal recipients did not exhibit seroconversion during a three-year follow-up[28]. Until now, there is no report of hepatitis C transmission via cornea grafting, despite the fact that 7 out of 29 corneas from seropositive donors were found to express hepatitis C (HCV)RNA[29].

The bulk of evidence on disease transmission via cornea transplantation consists of the data mentioned above. Eye bank associations and governmental institutions in many countries define their policies of tissue selection based on these data and substantial intuitive thinking. Usually, these policies are expressed in the form of lists of absolute and relative contraindications for use of donations. Absolute contraindications represent events that automatically exclude use of the corneas. Decisions based on relative contraindications are at the discretion of medical directors of eye banks. Lists of the Eye Bank Association of America are considered benchmarks in this context[30]. Irrespective of the origin of these lists, they usually deal with issues described below.

1. Eyes possibly exposed to hospital-acquired microorganisms

A matter of concern in donor selection corresponds to situations in which the patient underwent, before death, at least one of the following conditions: ventilatory assistance, septicemia, pulmonary infection, or immunosuppression. The preoccupation here is with graft contamination with hospital-acquired microorganisms and their transfer to the recipient. A report in the literature describes a typical case of an injured young man who received cardiorespiratory support for 26 hours before death. At hospital admission, he contracted bronchopneumonia due to *Diplococcus pneumoniae*. The two recipients of his corneas acquired endophthalmitis, and the two recipients of his kidneys died soon after surgery[31].

A study comparing ventilated and non-ventilated cornea donors revealed that the former indeed had a higher frequency of positive conjunctival cultures with a higher prevalence of mixed microorganisms. However, none of them transmitted an infection to recipient eyes[32]. In another study, the duration of ventilatory assistance did not influence contamination rate of corneoscleral buttons.

Even cases with positive button cultures had uneventful courses[33]. These results challenge the idea that patients assisted with mechanical ventilation before death are not eligible for corneal donation.

Septicemia is generally accepted as an absolute contraindication for tissue use because of the risk of graft-inducing endophthalmitis[34,35]. The problem is that high frequency of sepsis diagnosis, particularly in tertiary care hospitals, substantially increases the number of corneas discarded by eye banks. This drawback is often magnified by the fact that clinical manifestations of septicemia are frequently confused with those of the Systemic Inflammatory Response Syndrome, which includes trauma, burns, and other symptoms[36]. On the other hand, the strength of the association between septicemia and endophthalmitis is yet unknown. Reasons contributing to this situation include low incidence of septicemia even in cases of graft contamination[37,38], fortuitous parity of microbial profile between sepsis and its associated endophthalmitis[39,40], and the tiny proportion of intraocular infections of hematogenous origin[41].

A more conservative approach to septicemia would have to focus on the alleged pitfalls of this infection to the donor's corneas and recipient's eyes. One possibility is an increased chance of graft contamination. Another is the involvement of multidrug-resistant hospital-acquired microorganisms. If the concern is with the first prospect, it would be preferable to focus on fungal etiology because treatment of eyeballs with antifungal agents is not standard procedure in eye banks[42]. Bacterial contamination is an expected event which eye banks are usually prepared for it [2-5]. Conversely, if the concern is with hospital-acquired microorganisms, this would be a strong independent motive for discarding donations. However, because the critical issue is now the presence of fungi or resistant bacteria in donor blood, only these specific types of septicemia would qualify as absolute contraindications. Identification of such cases should be feasible because this information is regularly present in donor medical records. One may apply a similar reasoning to cases of pulmonary infection. If procedures of eyeball decontamination are practiced diligently, it is also unnecessary to include immunosuppression in the set of absolute contraindications.

2. Ocular abnormalities

The most common abnormalities found in medical records are glaucoma, anterior uveitis, intraocular surgery, refractive surgery, and keratoconus. The first three conditions affect corneal endothelium, and the others alter the curvature and the thickness of the cornea[43-45]. Medical record examination may be the only method of detecting glaucoma or initial keratoconus in the donor's eye.

3. Illnesses caused by slow viruses and prions

Slow viruses are viruses with an incubation period of months or years. They often cause diseases of the central nervous system that progress slowly and inexorably to severe physical and mental illness and fatal outcomes. The following conditions comprise this group: progressive multifocal leukoencephalopathy (John Cunningham virus), subacute sclerosing panencephalitis (measles virus), progressive rubella panencephalitis (rubella virus), AIDS, and rabies[46].

A notable example of this group is rabies because it has not only been reported to be transmitted via cornea transplantation, but it also presents higher diagnostic difficulty, particularly in regions where it is not endemic and therefore unexpected. Bronnert et al.[47] reported a case of a 26-year-old German female with rabies, whose mental state was confused with toxic cocaine psychosis due to the presence of the drug in her blood. Six patients received transplants of cornea, liver, lung, kidney, and kidney-pancreas from her. Three of them died of rabies over the next weeks; two recipients of cornea and one of liver survived. The latter received rabies vaccination a few years back and had detectable rabies-neutralizing antibodies in his serum prior to liver transplantation. The transplanted corneas were replaced and revealed no rabies virus. Despite this observation, the authors emphasized the risk of rabies transmission via corneal grafting, tabulating eight cases from the literature. They also pointed out that antibodies to rabies virus are rarely detectable in blood and cerebrospinal fluid at the time of hospital admission[47,48]. As a conclusion, they recommended exclusion of donors with neurological signs and symptoms, unless the cause of these phenomena are unequivocally explained by history, physical signs, and diagnostic tests. The probability of missing an AIDS diagnosis is smaller due to the better knowledge of its clinical manifestations and at-risk populations. Moreover, detection using post-mortem serological tests is possible in such cases.

Prions are membrane prion-proteins with an anomalous spatial configuration that induce similar proteins to assume their unusual shape[49]. They can spread insidiously through the brain for long periods of time. Once signs and

symptoms of mental and motor deterioration begin, the condition progresses rapidly to death. In humans, diseases caused by prions include kuru, Creutzfeldt-Jakob disease, Gerstmann-Straussler-Scheinker syndrome, and fatal familial insomnia. They may be of genetic, mutational, or acquired origin. Prions spread via ingestion of infected animal matter, blood transfusion, transplants, or poorly sterilized surgical material. These agents resist the commonly used methods for virus destruction. Diseases caused by prions are rare.

4. Neoplasms

Transmission of retinoblastoma via corneal transplant may be associated with presumed immune tolerance of the anterior chamber. If so, other intraocular tumors should present the same risk. Therefore, it is better to dispose of all eyes with neoplasia[50]. This measure is not expected to significantly affect the availability of corneas to eye banks due to the rarity of these tumors. Similar reasoning does not apply to systemic neoplasms as its carriers constitute a substantial source of corneas for transplantation, particularly in tertiary care hospitals. Their inclusion in the list of contraindications has a significant adverse impact on the productivity of eye banks.

Wagoner et al.[50] followed 73 patients who received 86 grafts from donors with various types of systemic malignancies for 127 months. They concluded that the risk of acquiring malignancy from corneas of those affected is the same as that of the general population and that exclusion of this source of donors was unjustifiable. This consideration extended to leukemias, except in cases where eyes had a high concentration of leukocytes in the anterior chamber. Also, they advised against transplanting corneas from individuals with neoplasia to immunosuppressed patients, as a precautionary measure. A more recent study has reached, in essence, the same conclusion[51].

5. Human T-Cell Lymphotropic Virus infections (HTLV)

Human T-cell lymphotropic virus (HTLV) was the first human retrovirus discovered. Out of four varieties, types 1 and 2 are the most important clinically. Both are involved in epidemics affecting 15-20 million people worldwide[52]. The majority of carriers are asymptomatic and therefore are identified only during screening for viral diseases. HTLV-1 has the potential to cause adult T-cell leukemia, myelopathy[53], retinopathy, choroidopathy, keratopathy[54], skin infections[55], xerostomia, and cracks in the tongue[56]. HTVL-2 has been found responsible for neurological abnormalities[57] and chronic lung infections[58], but without concrete evidence. Because both can spread via breastfeeding[59], sexual intercourse[60], venous infusions[58], transfusions[61], and even transplantation of solid organs[62], there is suspicion regarding their spread via corneal grafting. This concern typically pops up in all diseases where a virus may be involved, such as Burkitt's lymphoma (Epstein-Barr)[63], severe cytomegalovirus diseases[64], etc.

The fact that corneas infected with HIV and HCV[26,29] have been transplanted without seroconversion of recipients suggests that corneal grafting is not an efficient vehicle for viral transmission. An investigation specifically directed at assessing the risk of transmission of cytomegalovirus via corneal transplantation showed no difference in seroconversion rate based on whether the donor was infected or not with the virus. In addition, seroconverted patients did not show clinical signs of disease[65]. These results contrast sharply with those of solid organ transplants, where the risk of seroconversion in those receiving grafts from infected donors is 60% to 100%, and virus acquisition often leads to severe and lethal diseases[65,66].It is reasonable to speculate that a substantial part of the difference in risk between corneal and solid organ transplants is due to routine use of immunosuppressive therapy in the latter group.

Probably, the best approach for assessing risk of graft-to-host disease transmission by corneal transplantation is to focus on current evidences about the prospects of serious harm to recipients due to virus transmission via corneal transplantation. In rabies, the chance of severe harm seems to be indisputable. However, with agents such HTLV, Epstein-Barr, and cytomegalovirus, transmission is more likely to result in asymptomatic seroconversion, which is the most prevalent form of manifestation of these conditions in individuals with normal immunity. Following this reasoning, it would be wiser to center the attention on the etiological agent rather than on donor's ailment. This understanding would be consistent with present knowledge about disease pathophysiology, which shows that systemic conditions associated with viruses of ubiquitous distribution and asymptomatic course lead to serious illness only under a favorable combination of constitutional, genetic, environmental, and behavioral factors.

6. Hepatitis and jaundice

Hepatitis results from infectious causes (viruses, bacteria, fungi, protozoans) and non-infectious causes (alcohol,

drugs, metabolic disease, and autoimmune disease). The risk of transmission of hepatitis through corneal grafting mainly involves chronic viral hepatitis, caused primarily by the HBV and HCV viruses. Their carriers can spread the viruses for several years through blood and contaminated material. Post-mortem serological tests for these types of hepatitis are critical in differential diagnosis of cornea-donor jaundice. Even when bilirubinemia courses with a negative serology for viral hepatitis, one still has to consider the possibility of septicemia.

7. Other disorders

Other disorders subgroup mainly includes entities of unknown etiology such as Reye's syndrome, amyotrophic lateral sclerosis, Parkinson's disease, multiple sclerosis, and Guillain-Barré syndrome. Their inclusion in the list of contraindications is speculative. The justification that they may be of viral etiology is weak, for reasons already discussed in previous sections. Other components of this subgroup comprise diseases of known etiology and questionable practical importance which, theoretically, may be transmitted to corneal recipients[67].

FINAL CONSIDERATIONS

Although the lists of contraindications are not free of subjective reasoning, they play a fundamental role in standardizing criteria for corneal selection, reinforcing the necessity of analyzing tissues thoroughly prior to their transplantation. These lists are the guardians of the Hippocratic principle, "*primum non nocere*." However, each transplantation carries the risk of transmission of potentially harmful agents to the recipient. The aim of these procedures is not to eliminate this risk, but limit it to a reasonable level. Balance between tissue safety and availability needs to be maintained by exercising prudence without disproportionate rigor. Literature shows that knowledge acquired from and applied to high-income societies may be inadequate or even harmful when automatically transferred to low-income cultures[68,69]. Thus, despite the existence of invaluable information derived from places with significant experience in eye banking, each country needs to define its own policy on this matter, based on methodical scrutiny of local needs. Finally, the most common mistake in tissue selection is the extrapolation of experiences from solid organ transplants to corneal transplants; the cornea is avascular, and the person who receives it is not usually immunosuppressed.

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