DOI: 10.15825/1995-1191-2020-1-50-54

SCREENING OF CADAVER CORNEA DONOR FOR INFECTIONS IN THE EYE BANK OF THE FYODOROV EYE MICROSURGERY FEDERAL STATE INSTITUTION

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Objective: to analyze negative laboratory results of cadaver cornea donor screening during preparation of corneas for transplantation according to data from the internal registry of donors of the eye bank (EB) of the Fyodorov Eye Microsurgery Federal State Institution and the European Eye Bank Association (EEBA) from 2011 through 2015. **Materials and methods.** Data analysis was carried out using the internal registry of EB donors and the EEBA annual directories. The analyzed data included the number of eyeballs obtained, the frequency of incomplete tests (hemolysis for EB) and positive serological results for human immunodeficiency virus (HIV-1 and HIV-2), viral hepatitis B, viral hepatitis C and syphilis. **Results.** In just 5 years, the EB received 3,479 eyeballs. After hemolysis of donor blood samples, 13.9% (n = 486) of corneas were excluded from the EB. EEBA recorded fewer inconclusive tests during the same period. After hemolysis and positive serological tests, 19.4% (n = 676) of corneas were excluded from the EB. Overall, the number of positive serological tests in EBs was far higher than in the EEBA data. Frequency of positive HIV tests (HIV-1 and HIV-2) and syphilis in EB showed low variability annually, while incidence of hepatitis B increased in 2015. For the analyzed period, positive serology for hepatitis C was found to be prevalent among EB donors. Mixed infections were quite often recorded in blood samples. **Conclusion.** Based on analysis conducted, positive serology and hemolysis were the main contraindications and led to exclusion of 33.3% (n = 1162) of cadaver donor corneas received in EB. Frequency of positive serological tests for indicated infections in EB was higher than in the EEBA data, with significant predomination of hepatitis C.

Keywords: corneal transplantation, eye bank, serological tests, human immunodeficiency virus, hepatitis B virus, hepatitis C virus, syphilis.

INTRODUCTION

The eye bank (EB) of the Acad. S.N. Fyodorov Eye Microsurgery Federal State Institution was founded in 1988 to improve the practice of cornea donorship in the USSR (the Order of Academician S.N. Fedorov, General Director, No. 150 of 21.11.1988). Since 1995, the EB has possessed full membership in the European Eye Bank Association (EEBA) [1], taking an active part in the Association activities including its annual conferences. Currently, the EB prepares donor tissue for all types of keratoplasty and plays a key role in cornea transplantation in Russia.

Infection screening as an integral part of the EB work aims at preventing infectionstransmission from donor to recipient through a cornea transplant. The practice reports two cases of transmission of hepatitis B virus through a cornea transplant from a donor positive for the "Australian antigen" are known in [2]. At the same time, cases of transmission of human immunodeficiency virus (HIV) type 1 and 2, viral hepatitis C, and the syphilis causative agent through cornea donor tissue have not yet been reported [3, 4]. Taking into account the extreme importance of screening for infections at preparing and preserving a cornea transplant, the EB examines blood samples from each donor enrolled for these infections according to the licensing regulations.

In accordance with the Algorithm for preparing human cadaver cornea for transplantation [5], expert pathologists in thanatology departments perform initial screening of post-mortem donors. Donors bearing traces of injections on the body, tattoos, patients with tuberculosis, those died from burn injuries, as well as in cases of prescription of biological death of over 24 h and over 70 of age, are excluded. The EB receives the donor material in the form of eyeballs after enucleation by the thanatological service. Mandatory is the serology of blood samples from each donor. These biological materials are delivered in a sealed container and stored at +40 °C until the results of serological tests are ready. All blood samples received from cadaver donors are serologically tested for HIV (type 1 and 2), viral hepatitis B, viral hepatitis C, and syphilis. Thuis is done in the clinical

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laboratory of the Fyodorov Eye Microsurgery licensed to work with group III–IV group infectious pathogens. Samples with hemolysis and positive results for indicated infections are disposed of in accordance with the Russian SanPiN (Sanitary Rules and Regulations). Eyeballs from uninfected donors proceed to the next step to perform morphological and functional screening. Next, the transplantability index (morphological equivalent of a function) is determined, the corneoscleral disk is cut out and hypothermically preserved in the Borzenka–Moroz medium for subsequent clinical use [6].

In European Eye Bank Association, there is no single standard for harvesting donor corneas, though screening for infections is also performed for HIV (types 1 and 2), viral hepatitis B and C, and syphilis. Earlier, S.A. Borzenko has analyzed the infection of corneal cadaver donors for the period of 1996–2005 [6]. However, a comparative analysis of the incidence of the indicated infections for this period of time was not performed.

MATERIALS AND METHODS

Data analysis was carried out using the internal registry of EB donors and the EEBA annual directories. The analyzed data included the number of eyeballs obtained, the frequency of incomplete tests (hemolysis for EB) and positive serological results for human immunodeficiency virus (HIV-1 and HIV-2), viral hepatitis B, viral hepatitis C and syphilis.

RESULTS

From January 2011 to December 2015, the EB received 349 cadaver eyeballs with the median of 566 per year ranging from 556 (the 1st quartile) to 692 (the 3rd quartile).

Every year, hemolysis was the cause of utilization of 13.9% of the corneas by median (13.8–14.0%, quartiles 1–3) received in the EB. In the EEBA system, the term "Serology test inconclusive or impossible" is used, and according to the associationб the number of such tests was 2.0% (median) per year (1.2–2.1%, quartiles 1–3) (Fig. 1, b).

Positive HIV (types 1 and 2) tests in the analysis of blood samples in the EB were recorded in 1.2% of cases (median) with low variability over years: 1.1–1.7% (quartiles 1–3). In the EEBA, 3 times less positive HIV (type 1 and 2)tests were noted, with the median of 0.4% (Fig. 1, a, b).

Positive tests for viral hepatitis B in donor blood samples in the EB were recorded in 5.3% of cases (median) with a sharp, over twofold increase to 10.7% in 2015. In the same period, the EEBA recorded 2.9 times fewer positive results for viral hepatitis B (Fig. 1, a, b) with low annual variability.

Hepatitis C tests in the EB were positive in 12.1% (median) of donor blood samples with a peak of 14.5% in 2012, and a decline to 8.3% in 2014. In the same period, in the EEBA, the frequency of positive tests hepatitis C was 13.4 times lower than the median compared with the EB data. There was weak variability over the years and a general downward trend for this indicator. (Fig. 1, a, b).

Positive serological tests for syphilis in blood samples of donors in both the EB and the EEBA were weakly variable, though differing 7.7 times in median (Fig. 1, a, b).

DISCUSSION

In the EB, screening for infections of cornea cadaver donors helps prevent recipients from becoming HIV-, viral hepatitis B and C-, and syphilis-infected. The functioning medical and technological system of the EB provides for compulsory recording of the results of each serological examination performed at preparing a preserved cornea transplant. For thirty years of continuous daily work, the unique statistical data has been collected that allows to track the frequency of occurrence of the identified infections and hemolysis over a given period of time.

In 2011–2015, the EB hemolysis of blood samples of corpse donors resulted in rejection of 486 corneas, or 13.9% of the incoming material. In this period, the EB HIV seropositive tests (types 1 and 2), hepatitis B, hepatitis C and syphilis led to rejection of 676 corneas or 19.4% of the incoming material. In total, from 2011 to 2015, 33.3% of donors (n = 1162) has been excluded due to infections detected in the blood samples or due to hemolysis.

According to the results of the analysis, it was found that such infections as HIV, viral hepatitis B, viral hepatitis C, and syphilis occur, respectively, 3; 2.9; 13.4; 7.7 times more often according to the EB internal register compared to the EEBA data. This stress the fact such studies should take into account medical, social and other characteristics of the population [7]. Guided by the official data of the Federal State Statistics Service and the Ministry of Health [8], for 2011–2015, we have not found any correlation between the rate of positive serological tests and the incidence rate of the indicated infections (Fig. 2). In this regard, further study of the results of screening for infections of cornea donors in the eye banks of the Russian Federation is necessary.

CONCLUSION

In the course of the present study, it was found that from January 2011 to December 2015. the eye bank (EB) of the Fyodorov Eye Microsurgery Federal State Institution has received 3,479 eyeballs. All blood samples from cadaver donors were subjected to serology in the clinical laboratory of ща the Institute for HIV (types 1 and 2), viral hepatitis B and C, and syphilis. Serology showed 19.4% of seropositive donors, while hemolysis was detected in 13.9% of cases. Comparing these results with the data of the European Association of Eye Banks for the same period, seroprevalence of such infections as

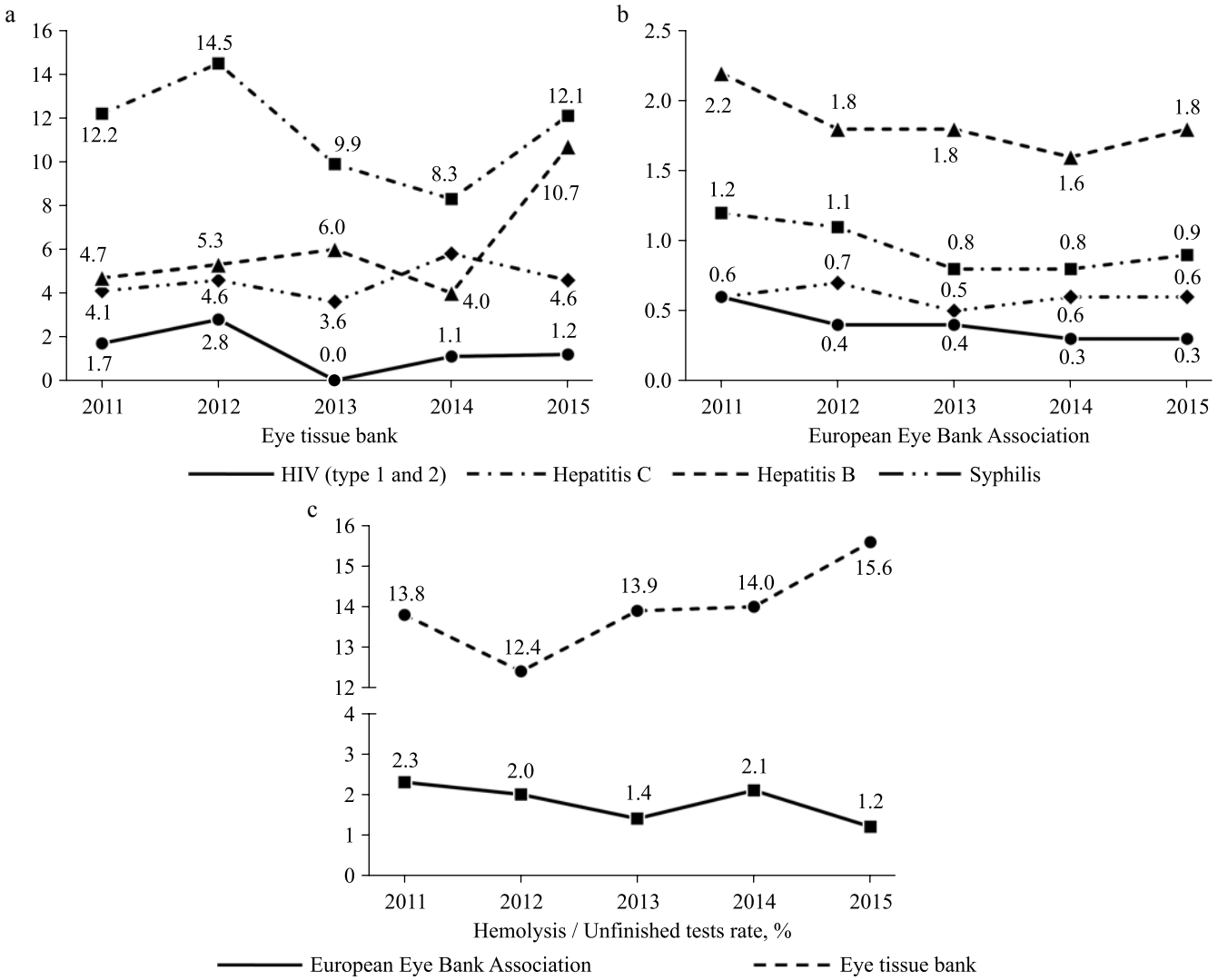

Fig. 1. Corneal donor screening results from 2011 through 2015. Rates of positive serology tests for human immunodeficiency virus (type 1 and 2), Hepatitis B and C viruses, and Syphilis in Eye tissue bank Eye Microsurgery (a) and European Eye Bank Association (b); rates of hemolysis in donor blood samples in in Eye tissue bank Eye Microsurgery and European Eye Bank Association (c)

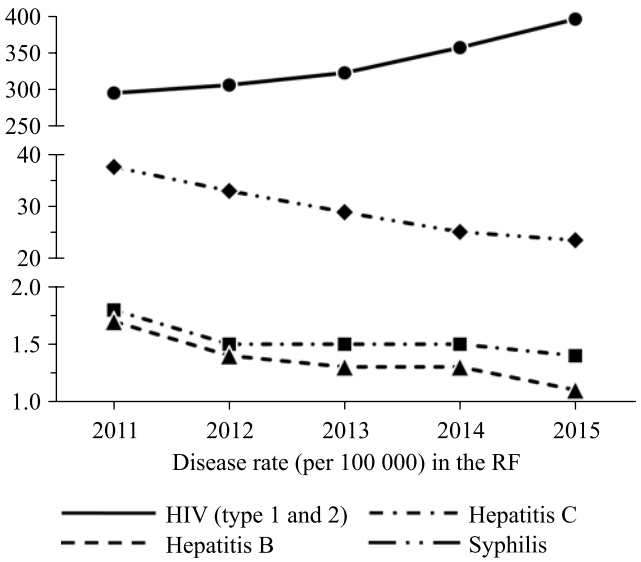

Fig. 2. Statistical data on the disease rate for human immunodeficiency virus (type 1 and 2), Hepatitis B and C viruses, and Syphilis in the Russian Federation according to the report of the Ministry of Health and Federal State Statistic

HIV, viral hepatitis B, viral hepatitis C, and syphilis was found to be higher in the EB donors. At the same time, no correlation was found between the rate of positive serology and the above infections rates in the population of the Russian Federation in 2011–2015.

Thus, screening for infections of cornea cadaver donors can prevent recipients to be infected with HIV, viral hepatitis B and C, syphilis, and develop prognostically significant algorithms for the prevention of recipient contamination with indicated hemo-transmissible infections in the eye banks in Russia.

The authors declare no conflict of interest.

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The article was submitted to the journal on 14.02.2019