ORIGINAL RESEARCH PAPER

Volume-7 | Issue-5 | May-2018 | PRINT ISSN No 2277 - 8179

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

STUDY ON FACTORS AFFECTING SEROLOGICAL TESTING OF CADAVERIC DONOR CORNEA IN A TERTIARY HOSPITAL IN WESTERN INDIA

Ophthalmology

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ABSTRACT

Background- The purpose of this study was to know the factors affecting serological testing of cadaveric donor cornea in a tertiary care centre in western India.

Methods- An observational cross sectional study was done for the period December 2014- December 2016. Variables studied included donor demographics (age, gender), cause & time of death of donor, macroscopic appearance of blood sample, and details of discarded tissues. Serological examination of blood was performed for human immunodeficiency virus, hepatitis B virus, hepatitis C virus, venereal disease research laboratory, and serology reports reactive or nonreactive were analyzed.

Results- During this study period, 200 corneal tissues were retrieved from 100 donors (male:female= 33:17). Most common age group of donors belonged to 70-79 year age group. The most common cause of death was cardiorespiratory arrest 63%. Macroscopically, sera were normal in 95% cases. Among 100 donors, 90% were nonreactive, 2% donors were found to be reactive to hepatitis B surface antigen (HBsAg), and 1% was reactive to HCV. 7% donors' sera were not fit for serological testing. Among all donors, 90% donors were accepted and 10% were rejected on the basis of serological testing. Cause of death and macroscopic aspect of sera influenced the serological results in a highly significant manner.

Conclusion- Macroscopic aspect of sera along with cause of death of the donor corneas play a vital role in corneal utility. Special care has to be taken by the enucleator as there is a significant risk of transmission.

KEYWORDS

Hepatitis B surface antigen (HBsAg), Hepatitis C Virus (HCV). HIV (Human Immunodeficiency Virus), VDRL (Venereal Disease Research Laboratory).

INTRODUCTION-

In India, there are an estimated 12.2 million blind people with vision ≤6/60 in at least one eye and of these, 1% have bilateral corneal blindness [1]. A large proportion of the corneal blind in the country is avoidable [2]. Cornea is avascular and immunologically privileged tissue due to which keratoplasty done for various corneal diseases is considered the most successful procedure.[3] Hepatitis B virus (HBV) is known to have been transmitted through corneal tissue, and there is always a risk of transmission of human immunodeficiency virus (HIV) and hepatitis C virus (HCV) infection from the seropositive eye donor though documented evidence of transmission of infection to the recipient does not exist. It is mandatory to perform venereal disease research laboratory (VDRL) for eye donors as it is a surrogate for the sexually transmitted diseases as positive syphilis serology correlates with the risk behavior. If the screening test is positive, a negative confirmatory test must be documented before tissue is released.[4] The cornea has been documented as the vehicle of transmission in 8 cases of rabies, 2 cases of HBV, and one case of Creutzfeldt-Jakob disease [5]. Positive serological results are one of the major reasons for discarding donor corneas[6]. Keeping this in mind in 1990, the Food and Drug Administration provided regulatory regime[7][8]. In heart-beating donors, sera samples are usually of good quality as emergency virological screening is done before organ harvest.[9]In contrast in cadaveric donors, sera are often of poor quality and frequently yield falsely positive results in serological assays as blood samples are collected at variable times after death[10]. Nonreliability of serological results leads to needless discard of these tissues which eventually enhance the shortage of corneal grafts. In cases of false-negative results, there are chances of transmission of the infection to the recipient or surgeon. Strict quality control can be accomplished with the selection of the donors, careful processing, preservation, and evaluation of parameters, such as donor serology by the eye banks (EB).[11] The purpose of our study was to analyse the factors affecting serological testing of cadaveric donor cornea.

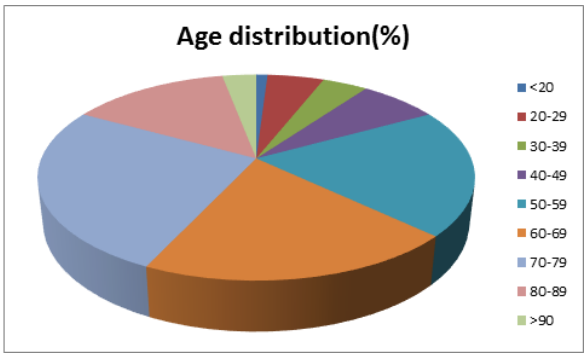
MATERIALS & METHODS-

An observational cross sectional analysis of eye bank records was done from (December2014-December 2016) in a two year period and analysed after obtaining institutional ethical committee approval. The variables of donor included donor demographics (age, gender), cause & time of death. Immediately after enucleation, about 3–4 ml of blood was collected by subclavian or internal jugular vein puncture using a sterile vacutainer. Serological examination of blood was performed for HIV, HBV, HCV, and VDRL. The cadaveric blood samples were received with storage at 2°C–8°C in microbiology laboratory and were tested and reported within 2-3 hours of collection. All the samples were analyzed for any macroscopic abnormalities such as hemolysis/turbidity or cloudiness or lipemic nature. The specimens of all sera were then screened for hepatitis B surface antigen (HBsAg), anti-HCV antibodies, and anti-HIV antibodies using rapid test. HIV testing was done as per National AIDS control organization protocol. All the tests were performed, and results were recorded based on the manufacturer's instructions. For detection of antibodies against Treponema pallidum, Rapid plasma reagin testing was done. The samples with macroscopic abnormalities were not accepted by the automated machines and error in the results was displayed. Those samples were considered unfit for serology. Reactive and nonreactive results were given depending on the clumping observed. Information regarding unfit and reactive samples was given to the eye bank which were discarded and incinerated by EB and personnel involved with enucleation were intimated. The data obtained were collected, analysed, assessed and tabulated and was entered into an Excel spreadsheet and then transferred to SPSS software (Statistical Package for Social Sciences, version 22, SPSS Inc, Chicago, IL, USA) for analysis. Statistical data were expressed in terms of means ± standard deviations. The descriptive statistics was used to express data in terms of frequency and percentage. Pearson Chi-square test (Fisher exact test) was used to find out the association between categorical variables. $P < 0.05$ was considered statistically significant.

RESULTS-

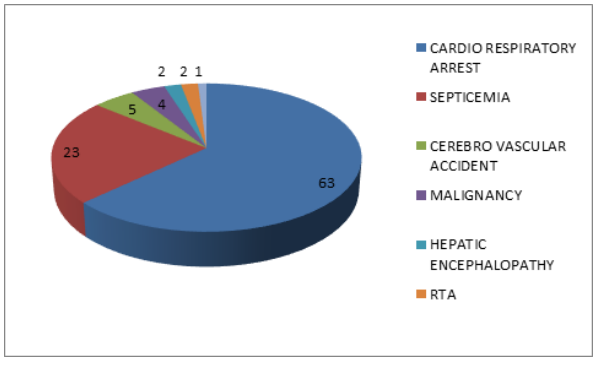
The mean age of donors was 63 years (range: 18-91 years). Most common age group of donors belonged to 70-79 year age group as depicted in Graph-1.

GRAPH-1



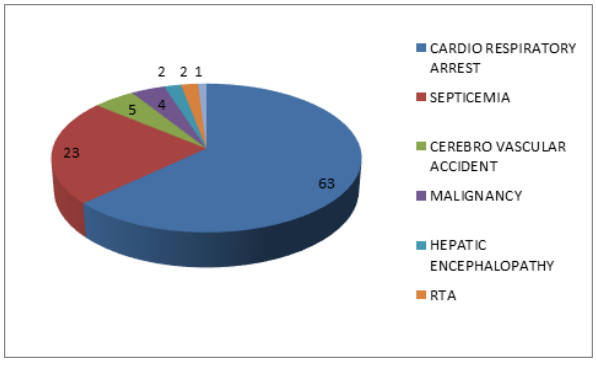
The most common cause of death was cardiorespiratory arrest (63%) followe by septicaemia being 23% as depicted in Graph-2.

GRAPH-2



Among the blood examined in serology 90 (90%) were nonreactive, 2 (2%) donors were found to be reactive to hepatitis B surface antigen (HBsAg), and 1 (1%) was reactive to HCV. The macroscopic aspect of the serum samples was noted in all 100 cases. It was considered normal in 95 (95%) cases and was abnormal, i.e., hemolyzed in 4 (4%) and turbid or lipemic in 3 (3%) donors. Overall total 7 (7%) donors' sera were not fit for serological testing as depicted in Graph-3.

GRAPH-3



Among all donors, 90 (90%) donors were accepted and 10 (10%) were rejected or discarded on the basis of serological testing. Serological results were influenced by macroscopic aspect of sera in a significant manner which were not conclusive (P = 0.00). This implicates the relationship between the macroscopic aspect of sera and the utility of the tissue which were actually excluded from utilization. 14 (7%) corneal tissues were discarded just on the basis of the macroscopically abnormal sera which were hemolyzed, turbid, or lipemic which were considered unfit.

DISCUSSION-

Jadeja and Bhatt *et.al* found that 69 (6.85%) of tissues could not be utilized and were incinerated as blood sample showed either reactive serology or insufficient or hemolyzed sera [12]. Seroprevalence of HBV and HCV viruses in eye donors was 2.4% and 0.2%, respectively and no case showed reactive serology to HIV and VDRL. Mahalakshmi *et al*. in a study done at Shankar Netralaya, Chennai, reported the seroprevalence of HBV and HCV as 3.52% and 1.45%.[13] Bhatt *et al*. reported seroprevalence of HIV, HBV, and HCV viruses in eye donors as 1.31%, 0.49%, and 0.49%, respectively, which is comparable to the present study.[14]In another study done by EB Association of Australia and New Zealand, the seroprevalence of HBV and HCV was 0.49% and 0.38% which is comparable to the present study.[7] HBV is known to have been transmitted through corneal tissue. HBVc DNA was detected in 6.6% of corneal epithelium and 14.8% of stromal epithelium of seropositive eye donors.[15]There is a significant risk of transmission of HBV to the enucleator and special precautions are required to be taken to handle HBV-infected tissue. HCV RNA has been detected in 34.5% in the cornea as well as in the tears and aqueous humor of seropositive patients; hence, it is essential to determine the infectious status of the eye donor with the virus. Since Hepatitis C is life-threatening, it is mandatory to screen potential cornea donors for HCV before transplantation.[5]With the current shortage in the corneal tissues great care must be taken during sample withdrawal as a hemolyzed sera on examination simply leads to the rejection of the donor cornea. With significant sero positive sera it is the responsibility of the eye bank to undertake strict quality control, safety and validity of the donor cornea.

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