



FACTORS AFFECTING THE UTILIZATION OF DONOR CORNEAL TISSUE IN A TERTIARY CARE EYE CENTRE IN CENTRAL INDIA.

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ABSTRACT **Introduction:** Corneal diseases are one of the leading causes of blindness in developing countries. There is a huge gap between demands and supply of cornea that has been further increased due to the COVID-19 pandemic raising the need for more donor corneas. This study was conducted to know the factors affecting the utilization of donor cornea for various purposes so that a targeted approach can be made to increase its utilization. **Method:** A retrospective observational study was conducted in a government eye bank of tertiary care eye centre for a period of 5 years. 163 Sero-negative corneas were studied for demographic details, cause of death, duration between death and enucleation, grading of donor cornea, duration, and media for storage of corneas were noted and data were analysed. **Results:** Out of 163 donor corneas, 97 eyes were utilized for transplantation and 66 eyes were used for research and training purposes. Out of 97 eyes for transplantation, 64 were used for optical purposes and 33 for non-optical purposes. 32.63% of optical grade corneas could not be utilized for transplantation because of contraindications. **Conclusion:** Utilization of donor corneas depends upon age, gender, grades of the cornea, death to enucleation time, cause of death as septicemia, malignancy, and is not affected by preservation to utilization time. Government awareness campaigns need to focus on the young population. We need to work on whether corneas from patients with demyelinating diseases can be utilized.

KEYWORDS : Donor cornea utilization, Penetrating Keratoplasty, Eye donation, Eye banking.

INTRODUCTION

Global Health Journal has documented that more than 36 million people across the globe are blind and about 217 million people are having moderate to severe vision problems. Alarming, the number of blind people worldwide is estimated to increase to 115 million by 2050.^[1] India with its population of 1.3 billion requires to target 100,000 corneal transplants, with 200,000 donor cornea collections annually to eliminate the burden of the backlog of corneal blindness in India.^[2]

The Andhra Pradesh Eye Disease Study 2003 reported a prevalence of 0.66% of corneal blindness in at least one eye and nearly 95% is avoidable. In India, corneal diseases affect 6.8 million people leading to the vision of less than 6/60 in at least one eye and both eyes are involved in approximately one million people.^[3] The existing gap between demands and supply of cornea with the current cornea procurement rate in India of 49,000 per year has been further increased due to the COVID-19 pandemic.^[4] With the current corneal collection rate, there is a need for more donor corneas to decrease this existing gap^[5]

Although in the last 10 years the rate of corneal donation has constantly increased in the pre-Covid era still the gap persisted. These donated corneas can be used for optical purposes, non-optical purposes for instance therapeutic/ tectonic grafting, and research or training purposes. The utilization of donated corneal tissue depends on various factors.

So, we undertook this study to know about the factors affecting the utilization of donor corneal tissue for various purposes and to know the causes of the non-utilization of the donated cornea for transplantation. So that a targeted approach can be made to decrease the gap and increase the utilization of donated cornea.

METHODOLOGY

The present study was conducted as a retrospective observational study in a government eye bank of tertiary care eye centre for a period of 5 years from 1st January 2015 to 31st December 2019 in central India. The study group included 175 eyes of 88 donors. 163 eyes with negative serology for Hepatitis B, Hepatitis C, Human Immunodeficiency Virus, and Syphilis were studied for utilization of donor corneal tissue. Demographic details were studied such as the

name, age, and gender of the donor. All the available medical records along with a detailed history of ventilator support were noted as per the proforma. The cause of death, time of death, and duration between death and enucleation were noted.

Grading of donor cornea was done according to EBAA, 1966, Saini JS et al. 1996 as excellent, very good, good, fair, and poor. Duration of storage, time of enucleation, and media for storage of corneas were noted.

The distribution of the donor corneas based on their utilization was grouped as mentioned in figure 1.

Data analysis was done using SPSS 20 software. Data was grouped and tabulated as frequency and percentage. Chi-square test was applied and a p-value < 0.05 was considered statistically significant.

RESULTS

In the present study out of 163 eyes, 97 eyes were utilized for transplantation, and the rest 66 eyes were used for research and training purposes. Out of 97 eyes that were utilized for transplantation, 64 eyes were utilized for optical purposes, 33 eyes for non-optical purposes.

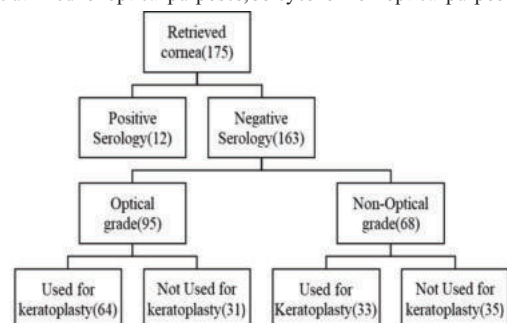


Figure 1: Distribution of retrieved cornea based on utilization

The most common cause of death amongst donors was cardiovascular arrest (35%) in the present study.

A statistically significant association between age group and donor cornea for utilization has been observed with $p < 0.01$. The youngest donor was 23 years old and the oldest donor was 87 years old. The mean age of the donors was noted as 54.95 years. Corneas obtained from younger donors were mainly utilized for optical purposes whereas corneas obtained from elderly age groups > 80 years were mainly utilized for research and training purposes. Table 1

Table 1: Association of various factors with utilization of donor cornea

Variables	Donor Corneal tissue utilization			P value
	Optical Transplant (64)	Non-Optical Transplant (33)	Training / Research(66)	
Age (years)	<40	36	0	0.01
	40-80	28	21	
	>80	0	12	
Gender	Male	48	12	0.007
	Female	16	21	
Ventilatory support	< 3 days	54	10	0.03
	> 3 days	10	23	
Death to enucleation time (hours)	≤ 6	33	13	0.037
	6-12	20	11	
	>12	11	9	
Preservation to utilization (hours)	<12	48	24	0.74
	>12	16	9	
Grading of donor cornea	good to excellent	46	13	0.01
	Fair to poor	18	20	
			35	

A significant association of utilization with gender was observed ($p=0.007$). The majority of male corneas were used for research followed by optical and among female donors, corneas were used for non-optical purposes followed by research purposes. Table 1

A significant association was observed between the grading of the cornea and its utilization with a p-value < 0.01 . Corneas with grading good to excellent were mostly used for optical purposes whereas corneas with grading fair to poor were used for non-optical and research purposes. Table 1

The present study observed a statistically significant association between death to enucleation time and corneal utilization ($p=0.037$), when enucleation was performed within 2 hours of death it was mostly utilized for optical purposes. However, no association of utilization of graft with preservation was observed ($p > 0.05$) (Table 1).

In the present study, 40.49 % of donor corneas were not utilized for transplantation instead were used for research and training purposes. The majority of non-transplanted corneas were because of septicemia followed by death due to unknown causes. Among the total of 95 optical grade donor corneas, 32.63% could not be utilized for transplantation purposes because of contraindications. Table 2.

Table 2: Reasons for Non-utilization of tissue vs grading of donor cornea

Reason	Optical Grade cornea (Excellent, Very good, Good)	Non- optical Grade cornea (Fair, Poor)	Total
Septicemia	9	19	28
Demyelinating disease	10	3	13
Malignancy	3	6	9
Death due to Unknown causes	9	7	16
Total	31	35	66

DISCUSSION

A retrospective study entitled "Factors affecting the utilization of donor corneal tissue in a tertiary care eye centre in central India" was conducted in the eye bank of tertiary care eye centre in central India.

In the present study, a majority (53.65%) belonged to the 40-80 years of age group, followed by 18.29% among the more than 80 years of age group and only 28.04% of donors belonged to less than 40 years of age

group. The mean age of donors in the present study was 54.95 years in the present study. Similar results were observed by **Jadeja JN et al** (2017), the majority of the donor was from the 71 to 80-year age group 135 (22%)^[6] **Singh SG et al** (2017) 58.28% maximum donors > 70 years of age group.^[7]

On account of increased awareness among the young population, eye donation has increased among the young population, but still, we are not getting enough corneas from young people as per the demand. As the quality of the corneas gets compromised with increasing age, most of the tissue cannot be utilized for optical purposes.

In the present study majority of donors were males with male: female ratio of 1.8. **Sugar J et al** (2009) also observed male predominance.^[8]

Male predominance could be attributed to more active social participation of males and more exposure to eye donation-related information, along with a higher literacy rate among males in India, no other significant role was observed.

The most common cause of death amongst donors in the present study was noted cardiovascular disease (45%) which can be attributed to a majority of patients belonging elderly age group of the present study. These deaths are natural, still, there is a lacuna in accidental deaths and young populations, making it the key area to work upon in the future.

Sugar J et al (2009) and **Patel et al** (2003) also observed cardiovascular disease as the cause of death in the majority of the patients, 60% and 50.5 % respectively.^[8,9]

Ventilatory support of more than 72 hours is known to decrease the viability of the corneal endothelium and compromise the quality of corneal grafts we have used the grafts with ventilatory support of more than 72 hours for tectonic and therapeutic purposes. Table 1

Jordan A Margo et al in their study observed that corneas with Ventilation time > 7 days had reduced cell counts affected and transplant quality was compromised.^[10] **John A. Seedor et al** observed no effect of ventilatory support on the quality of corneal graft in their study.^[11]

A significant association between enucleation time and utilization of corneal tissue for various purposes was observed ($p=0.037$). When enucleation was performed within 6 hours of death corneas were utilized for optical purposes, whereas cornea was utilized for research purposes if enucleation was done after 6 hours of death. Table 1

More exposure of the donor's eye to the environment after death and the release of more cytotoxic substances along with the growth of microbial flora affect the cornea both qualitatively and quantitatively. Therefore, there is a time limit for transplant donor corneas.

Raj A et al (2018) observed similar results as maximum keratoplasties i.e., 179 (50.28%) and 202 (56.74%) when death enucleation time was > 3 hours was statistically significant ($p < 0.01$).^[12] **Van Meter WS et al** (2005) also observed increased Death preservation time to be associated with an increased incidence of donor epithelial sloughing that adversely affects the survival of the graft.^[13]

More donated corneas (54.54 %) were utilized within 12 hours and fewer donated corneas (45.45%) were used after 12 hours of preservation in the present study. It was observed that there is no significant association between preservation to utilization time and utilization of graft for various purposes despite using the standard protocol of temperature maintenance and cold chain maintenance ($p > 0.05$). Table 1

Raj A et al (2018) observed similar results as maximum keratoplasties i.e., 56.74% when death to preservation time was ≤ 4 hours, which was statistically significant ($p < 0.01$).^[12] The donor corneas in the present study were graded as excellent, very good, good, fair, and poor based on EBAA, 1966. In the present study, good to excellent grades of the cornea were mostly used for optical purposes (28.2 %) whereas fair to the poor was used for research purposes (21.47 %) and the observed difference in utilization was significant ($p < 0.01$). Table 1

Raj A et al (2018) reported similar findings, Grade A cornea was used mainly for keratoplasty and poor grade for research and therapeutic

purposes ($p < 0.01$).^[12]

In the present study, 40.49 % of donor corneas were not used for transplant but were used for research and training purposes. The most common reason for non-transplantation of donor corneal tissue in the present study was found to be septicaemia followed by death due to unknown causes. Among the total of 95 optical grade donor corneas, 32.63% could not be utilized for transplantation purposes because of contraindications. Table 2.

Jadeja J et al (2017) also found septicaemia as the most common cause (42.3%) of non-utilization of donor corneal tissue for keratoplasty.^[6] This increasing trend of eye donation for research and training suggested that nowadays people are extremely motivated that their family members do not refuse to donate eyes even after knowing eyes cannot be transplanted in presence of some contraindications.

The limitations of this study were a small group population that could not specify a geographic area. A large community-based study with defined geographic boundaries will help in revealing actual awareness and willingness of the population regarding corneal donation and also help in assessing the potential barriers which if overcome can help in improving the corneal procurement rate.

CONCLUSION

Utilization of donated cornea depends upon grades of the cornea, death to enucleation time, cause of death as septicaemia, malignancy, and is not affected by preservation to utilization time. The majority of donors belong to the 40-80 years of age group, Government awareness campaigns need to focus on the young population so that we can get more young donors in the future.

To decrease the male-female ratio of donors, we suggest that organ and cornea donation should be taught in higher classes at the school level because at workplaces already females are, so it won't be making much difference to the existing gap.

Many good-grade corneas could not be utilized because of contraindications, we need to work on this field whether corneas from patients with demyelinating diseases after using newer steroids or immunosuppressants can be utilized.

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REFERENCES

- Bourne, RRA, SR Flaxman, T Braithwaite, MV Cicinelli, A DAS, JB Jonas, and et al. "Magnitude, Temporal Trends and Projections of the Global Prevalence of Blindness and Distance and near Vision Impairment: A Systematic Review and Meta-Analysis" 5, no. 9 (2017): e888–e879.
- Oliva, MS, T Schottman, and M Gulati. "Turning the Tide of Corneal Blindness" 60, no. 5 (2012): 423–27.
- Dandona, L, R Dandona, M Srinivas, P Giridhar, K Vilas, MN Prasad, and et al. "Blindness in Indian State of Andhra Pradesh" 42, no. 5 (2001): 908–16.
- Dandona, R, L Dandona, TJ Naduvilath, CA McCarty, and GN Rao. "Awareness of Eye Donation in an Urban Population in India" 27, no. 3–4 (March 1999): 166–69.
- Gyanchand, R. "Analysis of Donor Cornea Retrieval Data—Hospital and Residences." 4, no. 53 (2017): 3263–70.
- Jadeja, JN, and RV Bhatt. "An Analysis of Tissue Utilization at a Tertiary Care Institute Associated Eye Bank to Improve Tissue Procurement and Tissue Utilization." 5, no. 2 (2017): 85–90.
- Singh, SG, DR Satani, AP Patel, and DC Doshi. "Evaluation of Quality and Utility Rate of Donor Corneal Tissue Received at Tertiary Eye Care Center." 5, no. 2 (2017): 133–36.
- Sugar, J, M Montoya, M Dontchev, JP Tanner, R Beck, S Gallagher, and et al. "Donor Risk Factors for Graft Failure in the Cornea Donor Study" 28, no. 9 (October 2009): 981–85.
- Patel, HV, NH Brookes, L Moffatt, T Sherwin, S Ormonde, GM Clover, and et al. "The New Zealand National Eye Bank Study 1991-2003: A Review of the Source and Management of Corneal Tissue." 24, no. 5 (n.d.): 576–82.
- Seedor, John A., R. Doyle Stulting, Randy J. Epstein, Richard E. Nay, Neil G. Dreizen, George O Waking, Louis A. Wilson, and et al. "Survival of Corneal Grafts from Donors Supported by Mechanical Ventilation" 94, no. 2 (February 1987): 101–8.
- Margo, Jordan A., Martha F. Whiting, Clayton H. Brown, Caroline H. Hoover, and Wuqas M. Munir. "The Effect of Chronic Pulmonary Disease and Mechanical Ventilation on Corneal Donor Endothelial Cell Density and Transplant Suitability" 183 (2017): 65–70.
- Raj, Anuradha, Garima Mittal, and Harsh Bahadur. "Donor Factors Influencing Corneal Tissue Utilization in North India." 10, no. 2 (2018): 44–49.
- Van Meter, Woodford S, Douglas G Katz, Harrison White, and Robert Gayheart. "Effect of Death-to-Preservation Time on Donor Corneal Epithelium." 103 (December 2005): 209–22.