

Procurement, storage and utilization trends of eye banks in India

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Purpose: To study the trends in collection, storage and utilization of donor corneas in eye banks in India. **Methods:** The data was collected from 12 eye banks in India that collected more than 1000 corneas per year. The retrospective analysis of the parameters like characteristics of the donor and the host, storage media used, number of eyes collected, number of eyes utilized, causes of non-utilization of the tissue and the procedures performed was done. **Results:** A total of 20,564 eyes were collected by the 12 eye banks during the year 2013–2014. Voluntary eye donation (VED), and hospital cornea retrieval program (HCRP) contributed to 59.6% and 40.4% of tissue procurement respectively. Whole globe enucleation (52.3%) was more commonly performed as compared to in-situ excision of the donor corneas. The most commonly used storage media at all eye banks was McCarey-Kaufman (MK) media (83.3%). The utilization rate of the donor eyes was 50.5%. The most frequent indication for corneal transplantation was infection (active infection - 33.13%, healed infection - 10.78%) followed by Pseudophakic bullous keratopathy (PBK) (13.57%). Full thickness keratoplasty (optical penetrating keratoplasty - 47.23%, therapeutic penetrating keratoplasty - 31.74%) was performed most often followed by endothelial keratoplasty (12.41%) in the developing country. **Conclusion:** VED still contributes to majority of the donor tissue retrieval in India. The majority of the eye banks still utilize whole globe enucleation technique and store tissues in MK media. Trends from previous years showed a change towards HCRP, in-situ excision technique and preservation in the long-term storage media.

Key words: Corneal blindness, corneal transplantation, eye bank

Corneal blindness is the third leading cause of blindness after cataract and glaucoma in the world.^[1] In India, it is estimated that there are approximately 6.8 million people who have vision less than 6/60 in at least one eye due to corneal diseases; of these, about a million have bilateral involvement.^[2,3] It is estimated that approximately 20,000 patients with corneal blindness are added to the backlog each year and that 50% of corneal blindness is treatable.^[4,5] Many of these corneal blind patients may be visually rehabilitated by corneal transplantation.

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An efficient and precise utilization of the donor corneas in developing countries like India is only possible after a complete knowledge of the collection, storage and utilization of donor tissues. Thus, this study was conducted with the objective of identifying trends in collection, storage and utilization of corneal tissues in the top 12 eye banks in a developing country that had collected more than 1000 donor corneas per year.

Methods

A retrospective chart analysis of the data from all eye banks in India that have a collection of more than 1000 eyes per year was undertaken from April 2013 to March 2014. There are about 12 eye banks that are satisfied in these criteria. The research was conducted adhering to the tenets of the Declaration of Helsinki. A predesigned proforma was sent for completion to these eye banks. An evaluation of the donor and the recipient characteristics was done. The parameters evaluated were the number of eyes collected, the storage media used, number of eyes utilized and the number of eyes

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that are not fit for surgery. The causes for non-utilization of the donor eyes were also evaluated. The donor parameters evaluated were the donor age, sex, death to preservation time (DPT), and method of retrieval that is whole globe or in-situ excision. The recipient characteristics analyzed were the age, sex, indications for surgery and the type of the surgery performed.

Results

The total number of eyes collected by the 12 eye banks over a 12-month period (1st April 2013-31st March 2014) was 20,564. The average collection of eyes per year per eye bank was 1713 (range 1047-4652 eyes/year). The number of donor corneas procured through the voluntary eye donation (VED) program was significantly higher [59.6% (9492/15,926)] as compared to hospital cornea retrieval program (HCRP) [40.4% (6434/15,926)]. The whole globe enucleation was more commonly performed method [52.3% (8339/15,956)] as compared to the *in situ* corneo-scleral rim excision [47.7% (7617/15,956)]. A greater number of donors were present in the age group more than 60 years [65.2% (6504/9973)], followed by those between 30 to 60 years of age [26.3% (2625/9973)]. There were more male donors [59.5% (6074/10,210)] as compared to females [40.5% (4136/10,210)]. DPT was less than six hours in 77.3% (8497/10,999) of eyes whereas 6–12 hours in 18.1% (1992/10,999) of the eyes.

Majority of the eye banks reported use of multiple storage media for donor tissues. The most commonly used storage media was the McCarey-Kaufman's (MK) media (Aurora, Buffalo, NY) [83.33%], followed by the Moist chamber storage [50%], Cornisol (Aurolab, Madurai, India) [50%], Optisol (Baush and Lomb, St Louis, Missouri) [33.33%], Eusol (AL.CHI.MI.A.SRL, Padova, Italy) [25%] and Life 4^o C medium (Numedis, Isanti, Minnesota)[8.3%].

Of the total eyes collected, almost half [50.5% (10,387/20,564)] were utilized for corneal transplantation, out of which, 40.36% were non-optical grade whereas 59.64% were optical grade.

About 26 donor corneo-scleral rims had been used for more than one recipient. The eyes that are not suitable for surgery were used either for medical education [58.6% (4976/8351)] or for experimental research [40.4% (3375/8351)]. The data for the cause of non-utilization of tissues was available only for 291 eye [Table 1].

Most recipients were in the age group between 16 to 60 years of age [61.3% (5178/8449)] followed by those more than 60 years of age [26.5% (2241/8449)]. There were more male recipients [62.1% (3675/5921)] as compared to females [37.9% (2246/5921)].

The most common indication for corneal transplantation was infection (active infection 33.13% (2281/6884), healed infection 10.78% (742/6884)) followed by pseudophakic bullous keratopathy [13.57% (934/6884)] [Table 2]. Full thickness penetrating keratoplasty (optical penetrating keratoplasty 47.23% (4737/10,029)), therapeutic keratoplasty 31.74% (3183/10,029)) was the most commonly performed procedure followed by endothelial keratoplasty (12.41% (1245/10,029)) [Table 3].

Table 1: Causes of non-utilization of donor eyes

Causes mentioned	Number of donor eyes (n=291)	Percentage
Infiltration	98	1.9
Poor CD	54	1.1
Syphilis	40	0.78
HBV	24	0.45
Sepsis	24	0.45
HCV	22	0.43
Culture growth	12	0.24
HIV	8	0.16
Leukemia	4	0.08
Bad handling	3	0.06
Hemodilution	2	0.04

CD=Cell density (Endothelial count), HBV=Hepatitis B Virus, HCV=Hepatitis C Virus, HIV=Human immunodeficiency

Table 2: Indications for surgery

Indications for transplant	Number (n=6884)	Percentage
Active infection	2281	33.13
PBK	934	13.57
Healed keratitis	742	10.78
Failed graft	732	10.63
Keratoconus	376	5.46
CCO	339	4.92
Other dystrophies	320	4.65
Fuch's dystrophy	141	2.05
Degeneration	115	1.67
ABK	104	1.51
Congenital glaucoma	22	0.32
Other indications	778	11.3

PBK=Pseudophakic bullous keratopathy, CCO=Congenital corneal opacity, other dystrophy=Dystrophies other than Fuch's endothelial dystrophy, ABK=Aphakic bullous keratopathy

Table 3: Type of surgeries performed

Type of surgery performed	Number (n=10,029)	Percentage
Optical PKP	4737	47.23
Th PK	3183	31.74
DSEK/DSAEK	1245	12.41
DALK	437	4.36
Manual LK	193	1.92
Tectonic PKP	161	1.61
Boston KPro	73	0.73

PKP=Penetrating keratoplasty, Th PK=Therapeutic keratoplasty, DSEK=Descemet stripping endothelial keratoplasty, DSAEK=Descemet stripping automated endothelial keratoplasty, LK=Lamellar keratoplasty, KPro=keratoprosthesis

Discussion

There are more than 740 institutional members (Eye Banks and Eye Donation Centers) under the aegis of Eye Bank Association of India (EBAI). Out of these 15 eye banks i.e. 2% of the 740 organizations account for more than half of the total

collection. To meet the demand of the donor corneas, efficient functioning of the eye banks is necessary. High growth rates in the procurement of transplantable tissues, improved utilization rates, operating efficiency realization and increased financial sustainability are vital for successful functioning of an eye bank.

Most donors (65.2%) in our study were in the age group of age 60 years or older. The mean age of donors in past studies ranged from 42.7 years to 75.9 years.^[6-9] In our study, males were more as compared to that of females as has also been reported previously.^[10-12] Majority of donor corneas in our study were procured from the VED program as compared to HCRP. The higher age group of donors in VED program results in procurement of more eyes with non-optical grade quality. Due to paucity of good quality donor tissues, non-optical grade corneas are used for therapeutic keratoplasty in emergency.

Most eyes were retrieved within six hours of death (77.3%) however 18.1% of eyes were retrieved within 6 to 12 hours and remaining eyes were retrieved after 12 hours. The cause for delay was requirement of completion of formalities in medico legal cases before retrieval. Woodford *et al.*^[13] showed that DPT longer than 6 hours was more likely to result in sloughing of the donor epithelium. Even though the majority of the tissues were collected early within 6 hours, the major factors behind such low utilization rate could be lack of protection measures after death to prevent exposure as well as contamination of the eye, largely due to lack of awareness among the health care professionals.

Whole globe enucleation was still widely performed in more (52.3%) donors as compared to *in situ* corneo-scleral rim excision (47.7%). Kim *et al.*^[14] and Jhanji *et al.*^[15] compared the two techniques in a large, single eye bank series and found that *in situ* excision was equivalent to whole-globe enucleation when various parameters such as endothelial cell counts, ultrasonic corneal pachymetry, microbial contamination, graft clarity, and postoperative median visual acuity at the end of 3 months were studied. Although *in-situ* excision is the most preferred method worldwide, whole globe enucleation is still prevalent in India. The utilization rate in our study was only 50.5% of the total eyes collected. This is much lower as compared to other international eye banks.

The New Zealand Eye bank study reported 90% of donor corneas suitable for transplantation with a high utilization rate of 88%.^[10] This lower rate of utilization in developing countries can be explained by two reasons. Firstly, the most commonly used storage media is MK media (83.33%) in our study, organ culture is the most widely used method of storage in European countries and Optisol is the most common in America (USA). Secondly, these medium term storage media suffice our needs since the most commonly performed keratoplasties are for therapeutic or emergency indications while elective procedures are the most common in Europe and USA where long-term storage media are well suited.

In our study, 1.82% of tissues were discarded in view of positive serology (Human Immunodeficiency Virus, Hepatitis C virus, Hepatitis B virus or Syphilis). This is in contrast to a study by Viegas *et al.*^[16] who discarded 33.4% of corneas in their study due to positive or inconclusive serological tests. Cahane *et al.*^[17] reported 6.7% of discarded corneas due to HCV positive serology in contrast to this study where only 0.43% of corneas

were HCV positive. They reported that a delay in harvesting of donor corneas might give rise to a false positive HCV serology, which may be partially responsible for the high rate of HCV positivity among the donor corneas, with consequent tissue wastage.^[17] As most of the corneas in our study were retrieved within six hours, this may have led to a lower rate of positive HCV serology. Armstrong *et al.*^[18] reported the prevalence of HBV, HCV and HIV to be 0.25%, 0.93%; and 0.031% in the donor corneas. These values were closest to the results of our study. The prevalence of these results may vary depending on the prevalence of the disease in various geographical regions and also different diagnostic tests that may have been used.

More than half of the recipients in this study were between 16 to 60 years of age group with male preponderance. Cunningham *et al.* reported similar results in their study with the median recipient age of 45 years and 54.0% of recipients as male.^[11] The most common indications for corneal transplantation in our study were active infection (33.13%) constituting about one-third of the recipients followed by PBK and healed keratitis. Keratoplasty was most commonly performed for cases of infection, which were either acute or healed. High rate of therapeutic keratoplasty performed for active infection may be due to a delay in initiation of treatment and late referral to tertiary eye care centres. According to a study that had been previously conducted in India, the leading indication for penetrating keratoplasty was corneal scarring due to healed keratitis (38.03%) followed by acute infectious keratitis (28.38%).^[19]

PBK has been the leading indication for keratoplasty in the western world however; it is the second most common cause for keratoplasty in our part of the world constituting 13.57% cases.^[20] Keratoconus is also a leading cause reported in developed countries however; it accounted for only 5.46% of our cases.^[11] Pediatric keratoplasty was performed in only 5.24% of cases in our study. The reason for high rate of patients operated for graft failure (10.63%) in this study was due to poor quality donor corneas being utilized for therapeutic keratoplasty, which then have to be operated at a later stage with an optical quality graft.

In our study, penetrating keratoplasty (78.97%) remains the most common surgery that was performed in three-fourth of the patients. Cunningham *et al.* reported penetrating keratoplasty in 90.7% of the recipients.^[11] However, during the latter half of their study there was a progressive shift in transplantation type, with deep anterior lamellar keratoplasty and Descemet stripping endothelial keratoplasty combined accounting for 32.3% of all transplants in the final year of the study period. Endothelial keratoplasty is now the most common keratoplasty procedure performed in the United States with the most common indication being Fuch's dystrophy.^[21] Comparing our data with the last year data (unpublished), we observe a similar increase in number of lamellar keratoplasty. This may be due to a greater number of surgeons acquiring the skills to perform lamellar corneal procedures.

Recently, Gain *et al.*^[1] conducted a global survey of corneal transplantation supply and demand in 148 countries. They reported that about 53% of the world's population had no access to corneal transplantation and only one cornea is available for 70 recipients in need indicating a vast shortage of corneal grafts. A total of 2,84,000 corneas were reported to be procured in

82 countries with approximately 185 000 corneal transplants being performed in 116 countries indicating a utilization rate of 65.1%. The maximum numbers of transplants were performed in Fuchs dystrophy (39%) followed by keratoconus (27%), and sequelae of infectious keratitis (20%). India constituted one of the leading countries in corneal procurement along with United States and Brazil (55% of total procurement). Also, maximum number of eye banks were identified in India (238), followed by the United States (84) and China (75) out of the total 742 eye banks. Though, the procurement of tissues and number of eye banks are amongst the maximum in India; the utilization rate is still low. Thus, there is a great need of increasing the utility of the donor corneas by eye banks in developing countries like India. This can be achieved with continued increase in donor procurement through HCRP system.

One of the major limitations of the study is that the questionnaire was completed by the eye bank itself. Thus, there could be a potential source of bias. Also, there are no uniform guidelines for recording of data in various eye banks of India. This could be another source of bias in the conducted study. In addition, being a retrospective study, the detailed data from all eye banks was not available like the data of the type of retrieval and method used out of the total eyes collected.

Conclusion

Continued assessment of all eye banks with periodic review of trends in eye donation would be required to effectively increase the procurement and utilization of donor corneas and to reduce the imbalance between the corneal transplant supply and demand. The cause of non-utilization must be reviewed yearly and continuous efforts should be made to minimize the same.

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Conflicts of interest

There are no conflicts of interest.

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