Original Article

Profile of donors and corneal tissue obtained through hospital cornea retrieval programme in a recently established eye bank of a tertiary care teaching hospital of Eastern India

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Abstract

Context: There is a global need for quality eye banking practices and sensitization of primary care physicians toward corneal donation. **Aims:** To evaluate performance of a recently established eye bank (EB) and quality of corneas obtained, and identify areas of improvement during procurement and utilization of donor corneas. **Settings and Design:** This retrospective observational study is based on records of corneas collected through hospital cornea retrieval programme (HRCP) in the EB of a tertiary care institution during the first 2 years of its establishment. **Methods and Material:** Data on demographic characteristics of donors, death-preservation interval, specular microscopy parameters of corneas, indications for utilization, and reasons for non-utilization of corneas were collected. **Statistical Analysis Used:** Means, standard deviation, range, frequencies, and proportions were analyzed. Spearman's correlation coefficient and Kruskal–Wallis test were applied taking $P < 0.05$ as significant. **Results:** The EB retrieved 54 corneas from 27 donors with mean age 42.3 ± 24.2 years. All tissues were preserved in Cornisol®. Majority (50%) of transplantable tissues had an endothelial cell density (ECD) between 2,000 and 2,500 cells/mm^2. ECD decreased significantly with increasing age (Spearman's ρ -0.747, $P < 0.001$; Kruskal–Wallis $P < 0.001$). Overall utilization rate of tissues was 87.04% (47/54), and utilizable corneas (50/54, 92.6%) were mainly used for optical purposes (34/50, 68%). **Conclusions:** Successful HCRP of the recently established EB has shown considerable promise in terms of quality and utilisation of corneas. There is need for active involvement of primary care physicians in contributing to increasing voluntary eye donation through awareness, advocacy, and social mobilization.

Keywords: Corneal transplantation, keratitis, penetrating keratoplasty, specular microscopy, surgery with high-risk ocular conditions

Introduction

Transplantation of corneal tissue donated by kin of deceased individuals to eye banks (EBs) is the key to treatment of corneal blindness across the world. However, while 12.7 million people are eligible for cornea transplant, only one cornea is available per 70 needed.[1]

Blindness due to corneal diseases has been given prime importance under the National Programme for Control of Blindness and Visual Impairment (NPCB&VI) of India.[2,3] Procurement of tissues and number of EBs are one of the highest in India among developing countries and second only to USA; however, the utilization rate is reportedly low. In

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India, blindness due to corneal causes affects an estimated 1.2 million people with a projected need for 100,000 transplants a year for which 200,000 tissues need to be harvested at the current utilization rates.[1] There is a great need of increasing utilization of donor corneas by EBs in developing countries like India. In the present day, the eye banking system is heavily dependent on continued increase in donor procurement through hospital cornea retrieval programme (HCRP), which offers several advantages such as easy accessibility to potential donors, reliable and detailed medical history and shorter death to preservation interval (DPI), and cost-effectiveness.[3-6] Recent data from the top 12 EBs of India show that the HCRP accounts for 40.4% (6,434/15,926) of all tissues collected.[4] However, the role of primary care physicians in this regard is unexplored.

Proper corneal procurement, preservation, and evaluation has great importance in affecting keratoplasty outcomes. Therefore, to ensure ongoing standards of care for the patients, there is a need to audit the functioning of existing eye banks periodically, evaluate the gaps between procurement, and utilization and scrutinize the reasons thereof.

An analysis of published data available through the Medline, Scopus, and Embase databases using the phrases "eye banking," "hospital cornea retrieval programme," "cornea procurement," "donor cornea storage and utilization," and "recently established eye bank" revealed that there are few comparable studies reporting data from early years of establishment of the EBs. To the best of the authors' knowledge, no report of any eye bank data from this state is available in peer-reviewed literature.

Hence, a need was felt to evaluate the performance of the EB after 2 years of its establishment to identify possible areas of improvement during procurement of donor corneas. This study aimed at evaluating the quality of corneas obtained through the HCRP of a tertiary care hospital in terms of donor characteristics, specular microscopy parameters of collected corneas, and the utilization and reasons for non-utilization of corneas as an overall indicator of the performance of EB. This study will provide a model for internal audit of the performance of newly established EBs for bridging the gaps between procurement and utilization.

Subjects and methods

Study design

The present retrospective cross-sectional study is based on records of all corneas collected in the EB of a tertiary care institution during the first 2 years of its establishment in August 2018. The study procedures followed were in accordance with the ethical standards of as per the tenets of Declaration of Helsinki, and the National Ethical Guidelines for Biomedical and Health Research involving Human Participants of the Indian Council of Medical Research.

Ethical clearance

Approval of the institutional review board was obtained for the study (institutional ethics committee letter number MF/875 dated 30/09/2020).

Method of tissue retrieval and evaluation

HCRP has been the source of corneas at the EB since its inception. Trained male nurses of the institution, acting as grief counsellors, educate and motivate the relatives of deceased individuals for cornea donation. If there are no contraindications, informed consent for eye donation is obtained from next of kin of all donors, using the consent form based on the standards of Eye Bank Association of India (EBAI).[4] Corneoscleral buttons are retrieved by a team of cornea surgeons, junior residents, and trained paramedics taking universal precautions. An acknowledgement certificate is given to the family of the deceased for the contribution.

The retrieved tissue is stored in Cornisol® (Aurolab, Madurai, India), brought to the site in an ice-pack filled carrier box. Corneoscleral buttons remain suitable for keratoplasty upto 14 days under refrigeration at 2–8°C.[7]

About 10 ml of blood is collected for serological tests of hepatitis B virus (hepatitis B surface antigen, HBsAg), hepatitis C virus (HCV), human immunodeficiency virus (HIV), and syphilis (venereal disease research laboratory test, VDRL).

Tissue is evaluated on a slit-lamp biomicroscope, and endothelial cell evaluation is performed using the non-contact specular microscope Keratoanalyzer (EKA-04, Konan Medical Inc. Japan). Employing the Konan CellChek® software, the Flex-Center™ method performs an accurate quantitative morphometric analysis of endothelial cells.[8] Cornea surgeons determine the final quality of the tissues.

Data collection

Data were collected on demographic parameters including donor age, relationship of next of kin who pledged the eyes, cause of death, and death preservation interval. Specular microscopy characteristics such as room temperature at the time of evaluation, endothelial cell density (ECD), standard deviation of ECD (SD_{ECD}), coefficient of variation in size (CV), Mean cellular area (MCA), and hexagonality ratio (Hex%) were recorded. Utilization characteristics including type of corneal transplantation, indication for corneal transplantation, and reasons for non-use of discarded corneas were also documented. The age range was divided into four age-groups and the ECD, CV, Hex%, MCA, and type of keratoplasty performed using the corneas were compared across them.

Statistical analysis

Data were entered into Microsoft Excel Spreadsheet (Microsoft Corporation, USA) and analyzed on SPSS version 23 (SPSS Inc, USA) wherein mean, standard deviation, range, frequencies, and

proportions were evaluated. Spearman's correlation coefficient was calculated for determining the relationship of ECD with age. Comparison of quality of tissue in different age groups was done using the Kruskal–Wallis test, considering $P < 0.05$ as statistically significant.

Results

During the period of study, the EB retrieved 54 corneas from 27 donors [Figure 1].

Donor demographics

Donors had a mean age of 42.3 ± 24.2 years (range 5–84 years); 19 donors were males and eight females. Most of the donors belonged to younger age group of 5–24 years (9, 33.3%; Figure 2). In the first year, 30 corneas were retrieved while in the second year, 24 corneas could be retrieved till March after which EB activities were discontinued because of the COVID pandemic.[9]

Road traffic accidents were the cause of death in most cases (10, 37.0%), followed by head injury (9, 33.3%) and cardiac arrest (4, 14.8%; Figure 3). Consent for donation was given in most cases by the brother of the deceased (10, 37%), followed by son (8, 29.5%) and father (4, 14.8%). The grandfather, grandson, husband, wife, and uncle gave the consent in one case each.

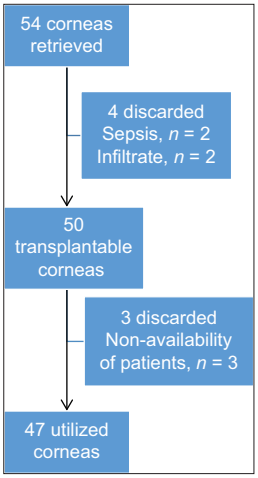

Figure 1: Flow diagram showing retrieval and utilisation of corneal tissues

A pair of corneoscleral buttons was retrieved in all cases. The mean death preservation interval was 3.5 ± 2 h (range 36 min to 7 h 35 min). All tissues were preserved in Cornisol within 6 h in summer and 8 h in winter as per EBAI standards.[5] Serological tests for HIV, HBsAg, HCV, and VDRL tests were found to be negative in all donors.

Specular microscopy parameters and correlation with age

Fifty corneas were evaluated by specular microscopy at room temperatures ranging between 20.0° and 27.9°C. The observed parameters are summarized in Table 1. Forty-one corneas (82%) had ECD more than 2,000 per sq. mm and were considered optical-grade [Figure 4]. Specular images could not be obtained for four corneas (7.4%), including one cornea that had to be transported out to another EB for tectonic keratoplasty for perforated corneal ulcer, even before specular evaluation.

ECD decreased with increasing age, and the correlation was statistically significant (Spearman's rho = -0.747, $P < 0.001$). The cell density was significantly greater in the first age group and showed a progressive decrease over successive age groups [Kruskal–Wallis $P < 0.001$; Table 2]. Cell volume and hexagonality did not vary significantly among age groups (P 0.281). Mean cell area increased significantly in successive age groups ($P < 0.001$).

Utilization of corneas

Overall utilization rate of tissues in EB was 87.04% (47/54, Figure 4). Of the seven corneas not used, one pair was

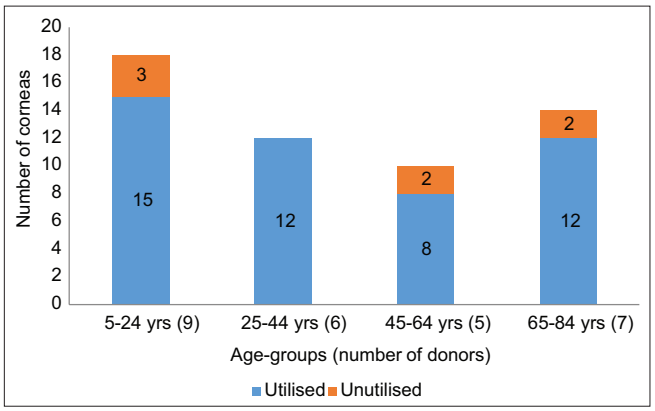

Figure 2: Age-group wise distribution of corneal tissues (N = 54)

Table 1: Specular microscopy findings of corneal tissues

	ECD	SDECD	CV	Hex%	MCA
All corneas (n=50)					
Mean±SD	2318.3±499.1	165.8±70.9	35.8±4.8	53.8±8.1	454.7±123.1
Median	2242.5	163.0	36.0	53.0	446.0
Range	1013.0-3745.0	89.0-554.0	26.0-56.0	30.0-75.0	267.0-987.2
Utilised corneas (n=46)*					
Mean±SD	2337.3±482.0	163.2±67.5	35.9±4.9	53.8±8.2	447.3±107.7
Median	2242.5	163.0	36.0	53.0	446.0
Range	1013.0-3745.0	89.0-554.0	26.0-56.0	30.0-75.0	267.0-987.2

CV: Coefficient of Variation, ECD: Endothelial cell density, Hex%: Hexagonality ratio, MCA: Mean cellular area, SD_{ECD}: Standard deviation of ECD. *In addition, one cornea was transported out to another eye bank without specular evaluation

Table 2: Age groups with distribution of specular microscopy findings

Specular microscopy findings (Mean±SD)	Age groups				Kruskal-Wallis test*	
	5-24 years (*n*=15)	25-44 years (*n*=12)	45-64 years (*n*=8)	65-84 years (*n*=11)	Adjusted *H*	*P*
ECD	2757.5±496.6	2336.9±250.8	2132.9±152.0	1913.5±344.7	23.479	<0.001
CV	34.1±3.9	36.0±2.9	36.1±2.4	38.0±7.9	3.821	0.281
Hex%	55.7±9.3	51.4±5.1	53.5±3.6	53.9±11.4	3.821	0.281
MCA	373.8±67.7	432.1±42.9	470.9±32.9	546.9±152.4	23.479	<0.001

CV: Coefficient of Variation, ECD: Endothelial cell density, Hex%: Hexagonality ratio, MCA: Mean cellular area, SD: Standard deviation. *df=3 in every case

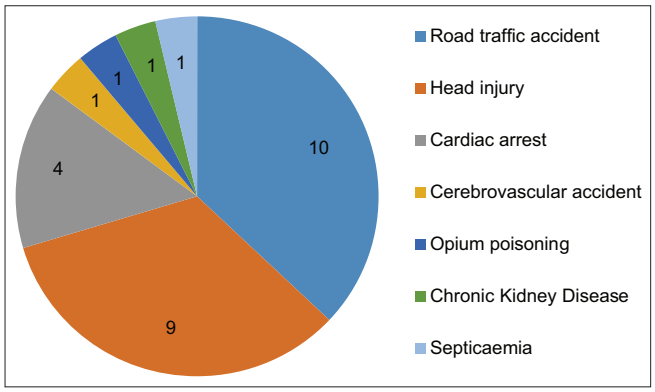

Figure 3: Causes of death of cornea donors (N = 27)

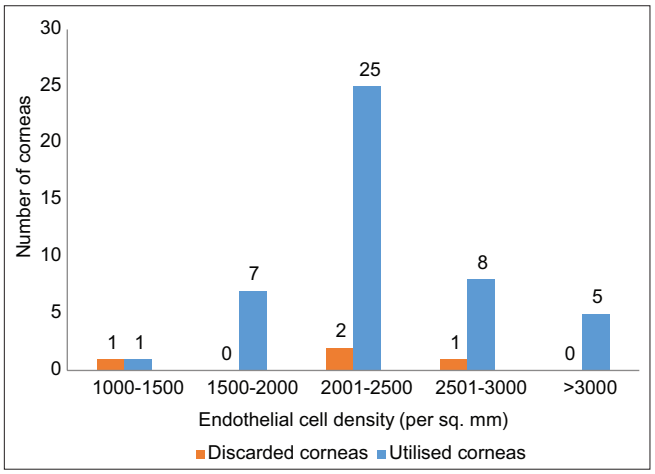

Figure 4: Endothelial cell density of donor corneas in the present study (n = 50)

discarded because of confirmation of sepsis in the donor subsequent to collection and specular evaluation of one of the corneas, while another pair had infiltrates. Of the utilizable corneas (50/54, 92.6%), three corneas remained unutilized because of non-availability of patients.

The corneas were mainly used for optical purposes; 19 optical keratoplasties and 15 triple procedures were performed (34/47, 72.3%; Figure 5). The most common indication was corneal opacity alone (19, 40.4%), followed by adherent leucoma (9, 19.1%), bullous keratopathy (4, 8.5%), and keratoconus (1, 2.1%). In this center, therapeutic keratoplasty was performed in 10 cases of corneal ulcer out of which four were perforated and one had impending perforation. Urgent re-surgery for failed graft was performed in one case. Component keratoplasty is not being done in this center as of now. One pair of therapeutic grade corneas were sent to another EB for urgent tectonic keratoplasties for two perforated corneal ulcers. All patients undergoing optical corneal replacement were transplanted with corneas with ECD >2,000 cells/mm^2.

Discussion

A recent nationwide survey of the Government of India involving 15,203 persons aged 0–49 years and 85,135 persons aged ≥50 years, found that corneal opacities cause 37.5% of blindness and 14.1% of visual impairment in the 0–49 years age group, and 8.2% of blindness and 2% of visual impairment in the ≥50 years age group.[2] Previous studies have stated the importance of individualization of blindness control programmes for different geographical areas to optimally utilize available resources. However, few comparable studies detailed early findings within first 2 years of establishment of EBs.[10-15] The largest EB of India started with only 20 corneal transplants in the year 1989.[11] In the present EB, 54 corneas were retrieved during the first 2 years of inception. Another EB in Eastern India collected 130 corneas in the first 2 years.[12] An EB in Turkey reported early data over 17 months stating a retrieval of 139 corneas from 70 donors,[13] while the Central Eye Bank of Iran managed to collect 856 corneas in its initial 2 years but did not state reasons for high procurement rate.[16] A study from New Zealand reported a collection of 206, while the Lions Eye bank of South Australia reported a collection of 198 in the first 2 years.[14,15] There is another EB and transplantation center in a public funded tertiary care institution in our city 10 km away, presently in its fifth year of establishment. It also receives voluntary donations and is supported by nongovernmental organizations. It is hoped that over time, this EB will also be strengthened in a similar way, as successful operation of EBs need effective awareness campaigns to increase voluntary donations.[15] Involvement of non-ophthalmic organizations and spiritual/religious leaders for community encouragement and mobilization are needed for increasing the number of donations.[3]

The present study shows that tissue collection was more in the first year of establishment than the second year while in all other studies the numbers increase with time.[10-15] This is due to suspension of eye banking activities with the advent of the SARS-nCOV-2 (COVID-19) pandemic after March 2020,[9,17] with resumption of limited collection activities after August 2020.[18]

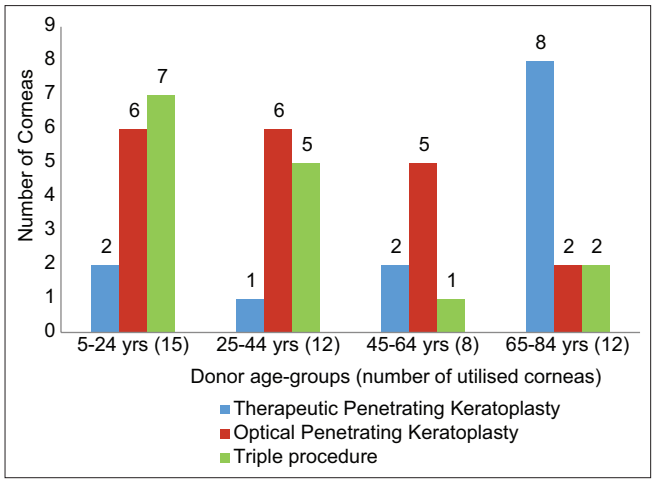

Figure 5: Age-group wise distribution of utilised corneal tissues (n = 47)

Studies from most EBs in other institutions report that the majority of donors were over 50 years of age.[10,14,19-22] Two studies from the western part of the country found this to be about 63 years.[23,24] A study from Germany reported a mean age of 68 ± 14 years while another study from Norway reported maximum donation from people aged 51–75 years.[25,26] In present study, majority (33.3%) of donors were in the 5–24 years age group. This was probably attributable to higher motivation of parents and caretakers when counselled about the higher possibility of utilization of tissue from these young donors due to less comorbidities and contraindications to transplantation. It has, however, been shown that clinical outcomes are not affected by donor age.[27-30]

Road traffic accidents and head injuries in this group were the commonest causes of death at 18.7% and 16.7%, respectively. The EB conducts HCRP in a tertiary level multispecialty hospital treating patients with severe morbidity. It also receives referred patients of polytrauma from all over the state. It has been found that tissues from donor deaths in road traffic accidents have a high transplantation rate.[6,20,22] Most EB studies that source corneas from voluntary donations as well as HCRP have reported cardiorespiratory failure as the commonest cause of death among cornea donors (30–64%) while trauma contributed 4–12.5%. [10,12,14,15,20,21,24]

The present study showed that all tissues were retrieved within 6 h in summer and 8 h in winter. These are consistent with the recommendations of the Joint Review of Eye Banking Standards of India, 2013.[5] The mean death-to-preservation interval in this study was 3.5 h with a median of 3 h. This was comparable to other studies from India which reported these to be 3.9 h and 2.8 h, respectively.[12,24] A study from Brazil had a mean DPI of 9.1 ± 4.7 h, while another from Turkey had 6.7 ± 2.9 h.[13,31] The norms for preservation vary according to the geography, warmer climates requiring lesser DPI for optimum outcomes. In temperate climates, a longer DPI may be acceptable. A study from Germany reported that the acceptable post-mortem enucleation time as long as 72 h.[25] In the study from São Paulo, the mean DPI was 10.2 ± 5.5 h.[22] Patel *et al.* from New Zealand had reported a DPI 15.2 ± 6.2 h with a median of 15.6 h while Krohn and Høvding from Norway reported a longer duration of 26 ± 15 h.[14,26]

Majority (50%) of the transplantable tissues had an ECD between 2,000 and 2,500 cells/mm^2; 82% had ECD >2,000 cells/mm^2 and 25.93% had >2,500 cells/mm^2. This is in contrast to a study in São Paulo wherein the prime reasons for rejection of corneas for transplant were related to age and low endothelial cell count.[22] The mean ECD was 2318.3 ± 499.1 cells/mm^2. This is apparently less than the data from New Zealand in which the average was 3024 cells/mm^2, however, their method of assessment included the peripheral endothelium (which has more endothelial cell density) and thus cannot be readily compared.[14,32] An Indian study found mean ECD to be 2,857 ± 551 cells/mm^2 with 68% having ECD >2,500 cells/mm^2[12] and another had a mean ECD 2708.93 ± 271.52 cells/mm^2[23] but the technique of assessment was not detailed. Routine application of the Flex-Center™ method of ECD count to the corneal optical zone may be the reason for lesser ECD values in this study. There is concurrence with the findings of Matsuda *et al.*, Patel *et al.*, Tufekci *et al.*, and Krohn and Høvding who observed similar significant association of increasing donor age with lower ECD.[13,14,26,30]

In a survey across 82 countries in the year 2016, Gain *et al.* found a utilization rate of 65.1%.[1] Overall utilization rate of corneas in the present EB was 87.04% which is comparable with the study from New Zealand (88%) and considerably higher than the national average of 50.5% as found from a study of 12 EBs of India that collect more than 1,000 eyes per year.[4,32] High utilization can be attributed to donor selection criteria and the policy of not harvesting tissues from donors with known contraindications for judicious use of resources and work force.[11] The residents have been trained to take all precautions and care to preserve the quality of tissues during the procedure. Due to hospital-based cornea retrieval, the medical history and serology of the patient is known by the time retrieval tends to take place.[3] Repeat serological tests for all corneal donors in this EB confirmed these results and no tissues had to be discarded on this account. Use of an intermediate time-span storage medium helps to allow enough time to call pre-registered patients from remote locations for keratoplasty and reduces wastage. Co-ordination with law-enforcement agencies and the department of forensic medicine in the institution helps speed up formalities in medico-legal cases, in contrast with the Nepal Eye Bank where such obstacles are met with.[33] In the present EB, there is proper co-ordination with the other EB in the city to provide required tissues and media when asked for. This is also in contrast to that reported in the North East England study where lack of utilization has been reported after corneas were issued, because the patient was unfit, unavailable, or no longer required the transplant.[34]

The utilization rate of transplantable tissues (94%, 47/50) in this study is comparable to that of the Nepal Eye Bank, which

is now completing 30 years of service. The latter utilizes 97% of transplantable tissues collected because of equitable country-wide distribution as well as sending of surplus tissues outside the country.[33] About 68% (34/50) of utilizable corneas were used for optical purposes including penetrating keratoplasty and triple procedure (cataract surgery with corneal replacement, 15/50). This is comparable to a study from the National Eye Bank in the apex institute of this country where optical corneal replacement was performed in about 60% of cases (106/177).[10] All patients undergoing optical corneal replacement were transplanted with corneas with ECD >2,000 cells/mm^2. However, it has been suggested that splitting and preparing the donor tissue within the EB may improve tissue validation and donor tissue availability, and may increase surgeon efficiency.[35] Such tissue is used in selective replacement of diseased layers of the cornea (lamellar keratoplasty), and is advantageous because of less intra-operative complication rate, better maintenance of globe integrity, and reduced risk of graft rejection in postoperative period as compared to full-thickness keratoplasty.[36] Thus, there is need to initiate lamellar tissue preparation in the EB as lamellar keratoplasty techniques may have a positive impact on the utilization rate of corneas in the future.[34]

Seven corneas were not utilized for transplantation, but used for training of residents instead. In one case, sepsis was confirmed by investigations after cornea removal and the pair of tissues could not be used. In another instance, a pair of corneas had infiltrates on the slit-lamp examination. Three corneas were not used because of failure of registered prospective recipients to turn up, citing reasons of engagement in agricultural harvest, floods, wedding season, or lack of leave from workplace and unavailability of subsequent suitable recipients. This is much less than previously reported by a study from a tertiary EB of north India, which documented yearly discard rate of 30–39% during the study period of 2011–2016.[37] However, to further reduce our discard rate, there is need to involve primary care practitioners and secondary-level healthcare institutions who could register and refer individuals with corneal blindness appropriately and timely. Primary care physicians must realize the responsibility to counsel patients and co-ordinate with higher institutions to make prospective patients avail of the opportunity for transplant whenever corneas are available. This would entail maintenance of a blindness registry at the primary care level with emphasis on individuals with curable blindness. Vision centers, health and wellness centres and primary care ophthalmic practitioners would also play an extremely vital role in this regard. A software-based management solution linking the patient waiting list with EBs and keratoplasty clinics has been suggested in Germany. Wide distribution of such a software among primary care physicians in India would ensure that all transplantable corneas are suitably utilized with minimal wastage, in addition to simplified recordkeeping and data analysis.[38] Increased co-ordination among EBs in the city or region for sharing of tissues and patients would also reduce wastage and increase benefits.[3] Establishment of collection centers at the secondary care level and their coordination with primary care practitioners could also help to strengthen procurement of utilizable corneas and help spread awareness about eye donation in the community. Primary care physicians can also serve as torchbearers for awareness regarding prevention of corneal blindness and about eye donation, as well as guiding needy patients to appropriate centres for corneal replacement.

In summary, this is the first study about functioning of an EB from our state. Successful HCRP of this recently established eye bank has shown considerable promise within the first 2 years in terms of the quality and utilization of corneas. However, there is need for increased awareness, advocacy, and social mobilization right from the level of primary health care. Active involvement of primary care physicians in contributing to increasing voluntary eye donation, due to their wide outreach and penetration to the grass root levels can lead to increased procurement and utilization of corneas. As there is a global need for quality eye banking practices, the present audit of early data from our eye bank can serve as a template for other newly established eye banks.[11]

Key Messages

Through hospital cornea retrieval programme, high utilization of corneal tissue was achieved in the newly established eye bank, attributable to donor selection criteria and the policy of not harvesting tissues from donors with known contraindications, for judicious use of resources and work force. There is need for sensitization and active involvement of primary care physicians in contributing to increasing voluntary eye donation through awareness, advocacy, and social mobilization.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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