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A preliminary descriptive analysis of Corneal Transplant Registry of National Eye Bank in India☆

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ABSTRACT

Purpose: To describe and analyze the Corneal Transplant Registry of National Eye Bank and also evaluate graft outcomes in India.
Methods: All patients who underwent corneal transplant at our center within six months of setting up of Corneal Transplant Registry and installation of database at National Eye Bank were included in the study. The established database was analyzed for utilization, donor and recipient details and graft outcomes. Outcome was assessed at the end of one year follow up. The influence of various donor and recipient factors affecting outcome were evaluated. Visual outcome was analyzed in terms of shift in visual handicap category. Statistical tests like analysis of variance, Kruskal–Wallis test and Chi square tests were applied for determination of clinical significance wherever required.
Results: 326 corneas were received from 168 donors; of these, 234 (71.7%) were utilized for transplantation. Out of 177 patients with adequate (one year) follow up (75.6% patients), optical corneal replacement was performed in106 patients and therapeutic keratoplasty in71. 78% (82/106) patients in the optical group retained clear grafts at the end of follow up. 59.7% (49 of 82) of patients who attained clear grafts belonged to visual disability category 3 or worse pre-operatively. 59.1% of these achieved BCVA of ≥6/60 at the end of follow up; thus shifting up their visual handicap category. Primary graft failure was found to be associated with full thickness keratoplasty and not with lamellar procedures ($p < 0.05$) and occurred in 4.2% patients (5) with optical corneal replacement whereas 7.5% patients (8) developed secondary graft failure. Age of donor ($p = 0.54$), death enucleation time ($p > 0.05$), cause of donor death ($p = 0.15$), type of surgical procedures ($p = 0.538$) and indication for surgery did not have any significant effect on outcome. 76% patients who underwent therapeutic graft achieved elimination of corneal infection.
Conclusions: The development of corneal graft registry established an effective means to evaluate our corneal transplantation services. Outcomes of sight restoring corneal transplants performed were comparable to results of graft registries from developed nations.

1. Introduction

According to the data released by the World Health Organization (WHO) in 2000, approximately 50 million blind people inhabit the world and nearly 150 million people suffer from 'low vision' [1]. The global data identified three major causes of blindness in the world, namely cataract, trachoma, and glaucoma [2,3]. Corneal diseases should primarily be prevented as the overall success rates remain poor when visual rehabilitation is offered with corneal transplantation [4–15]. In order to appropriately address the problem faced due to corneal blindness, there is a long felt need for individualization of blindness control programs to suit different regions and for optimum utilization of available resources. Therefore, we conducted this study to understand the nature and prevalence of corneal diseases in this part of the world, donor's personal and tissue characteristics, and the structural and functional outcomes of corneal replacement. To aid us in this endeavor, the National Eye Bank Corneal Transplant Registry was established with the aim of estimating the efficiency of the corneal services being provided.

2. Materials and methods

All consecutive patients presenting to our cornea clinic, Dr. Rajendra Prasad Centre for Ophthalmic Sciences, All India Institute

☆ Authors have full control of all primary data and they agree to allow Graefes Archive for Clinical and Experimental Ophthalmology to review their data upon request.

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of Medical Sciences (AIIMS), New Delhi, who underwent keratoplasty over six months from the date of establishment of the graft registry were included in the study. AIIMS is a public funded teaching hospital and tertiary care referral center in Northern India. It is representative of the population of India as a whole. Apart from a residency training program, it offers higher specialist training in cornea and all other subspecialty areas of expertise such as retina, pediatric ophthalmology and ophthalmoplasty. The National Eye Bank at the Dr Rajendra Prasad Centre for Ophthalmic Sciences is run by the central government dedicated to the procurement and distribution of corneal tissue for transplantation. It is the apex body of the National Program for Control of Blindness administered by the Chief of Dr. Rajendra Prasad Centre for Ophthalmic Sciences and the day-to-day activities and protocols are supervised by the Faculty-in-charge. The Eye Bank collects the eyes (i) of voluntary registered eye donors after their death, (ii) of those deceased persons when enlightened relatives agree to donate the eyes as a service to humanity, (iii) from hospital deaths and from post mortem cases, after motivating and obtaining the consent from the next of kin, and (iv) from the collection centers of the Institute. These eyes are processed by the Eye Bank and are supplied to eye surgeons for corneal grafting and other sight restoring operations.

Donor's personal and tissue details which included corneal procurement source, donor age, socio-demographic data, date and time of death, cause of death, death enucleation time (DET), serology details, and culture were recorded in the database. The procured corneas were clinically graded based on slit lamp biomicroscopy and endothelial count on specular microscope [16]. (Annexure 1) The recipient details included socio-demographic data, preoperative diagnosis, visual disability category and type of procedure performed. Indications for surgery were classified into (a) Optical purpose i.e. corneal replacement performed primarily to restore corneal clarity, (b) therapeutic purpose i.e. surgery performed to eradicate corneal infection and (c) tectonic i.e. surgery performed primarily to restore the integrity of the globe. Type of surgery performed was categorized as penetrating, triple (i.e. keratoplasty in addition to lens extraction and IOL implantation) and lamellar keratoplasty. Therapeutic keratoplasty is performed by faculty members specializing in cornea or Senior Residents who are qualified ophthalmologists with an MD or MS degree having already completed a three year residency program in ophthalmology and are undergoing a further three years of senior residency which is a higher specialist training in cornea and refractive surgery. Optical penetrating keratoplasty and lamellar keratoplasty are also performed by the cornea faculty and the Senior Residents assisted or supervised by the faculty.

Supplementary material related to this article can be found, in the online version, at http://dx.doi.org/10.1016/j.clae.2013.08.155.

2.1. Acquisition of clinical data and analysis of outcome

Patients were reviewed in corneal transplant follow up clinic at 1 week, 1 month, 3 months, 6 months and one year. At each visit patients were examined for their best corrected visual acuity and graft status. Adequate follow up was defined as at least 1 year follow up after surgery, others were categorized as 'lost to follow up' and the results of these patients were not analyzed. In relation to optical keratoplasty, success was defined as clear graft at the end of follow up, primary graft failure was defined as a graft which fails to clear in the early postoperative period ≤ 4 weeks, and secondary graft failure was development of corneal edema with or without irremediable loss of graft clarity in a previously thin and clear graft. Therapeutic keratoplasty was done in cases of active keratitis and perforated corneal ulcers and therefore usually require larger sized grafts in an already inflamed eye. Success in these cases is thus not defined on the basis of graft clarity which is difficult to achieve; but on the basis of eradication of corneal infection with no episode of recurrence. Maintenance of globe integrity was considered as successful outcome for tectonic keratoplasty at the end of one year. A complication was defined as any development which has the potential to compromise final graft outcome [17]. Visual outcome of the patients was analyzed by change in preoperative visual categories (up or down shift) (Annexure 2) [18,19].

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The effect of various donor and recipient factors on the outcomes of optical keratoplasty were evaluated using univariate analysis. Analysis of variance and Kruskal–Wallis tests were applied to evaluate the effect of donor age and DET on outcome. Chi square test was applied to know the effect of procurement source and type of surgery on graft outcome. Any difference with a p value of ≤ 0.05 in any of these variables was considered significant.

3. Results

3.1. Descriptive analysis of registry

Donor details: In the six-month period analyzed, 326 corneas were received from 168 donors. 234 (71.7%) were utilized for transplantation and 92 (28.3%) could not be used. Of these unutilized corneas 45/92 (48.9%) were not suitable for transplantation due to poor tissue quality. Other factors accounting for non utility of the tissue included serology positivity of donors, culture positivity of the tissue and inadvertent damage during the surgery. With respect to donor corneal retrieval sources, the Institute and its collection centers were the major providers of donor tissue constituting 73.8% of total cornea received. Contributions made by other Eye Banks and voluntary donors accounted for the rest of the 15.1% and 10.7% cornea, respectively. Ischemic heart disease was the most frequent cause of mortality amongst the donors (35%). Other causes included death due to cardio-respiratory failure (30%), stroke (6%) and road traffic accidents (4%). Mean age of the donors was 52.74 ± 22.7 years (range 15–95). Mean DET was 4.83 ± 2.91 h (range 45 min–14.5 h).

3.1.1. Recipient details

The average rate of performing keratoplasty at our institute was found to be 1.3 per day and of the 234 patients who received corneal transplants during the study period, only 177 (75.6%) patients completed adequate follow up and the remaining 67 patients were lost to follow up including 19 patients who underwent tectonic keratoplasty as a globe salvage procedure. Amongst these 177 patients, 106 patients had undergone elective sight restoration keratoplasty and the indication for surgery included post-infectious scar (36, 33.9%), keratoconus (11, 10.3%), bullous keratopathy (19, 17.9%), corneal dystrophy (12, 11.3%) regraft (12, 11.3%) and miscellaneous causes (16, 15.09%). Of these full thickness keratoplasty was done in 73, (68.8%) and lamellar surgery was performed in 33 eyes (31.2%). Of the lamellar surgery, 7 globes were used for two patients i.e. DSAEK and DALK/LK were done from the same donor cornea in 7 instances. The remaining 71 patients underwent emergency keratoplasty for active infectious keratitis which was relentlessly progressive and not responding to medical therapy leading to extensive corneal involvement and perforation or impending perforation. Diagnosis of patients with adequate follow up with respect to the type of surgeries performed is shown in Table 1. Success in optical group was achieved in 82 of 106 (78%) patients as primary and secondary graft failure occurred in 5 (4.2%) and 8 (7.5%) patients, respectively and non sight threatening complications developed in 11 eyes (10.3%) which included suture