

Clinical Profile of Patients Awaiting Keratoplasty in Northern India

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ABSTRACT

Background and objectives: Corneal blindness is a major public health issue, especially in developing countries like India. Our aim is to study the clinical profile of patients awaiting keratoplasty in a tertiary eye care centre in North India.

Methods: Retrospective analysis of the registration forms of the patients registered for keratoplasty over a period of one year at Dr. Rajendra Prasad centre for ophthalmic sciences, Delhi were included in this study. The variables studied were age, gender, geographic area, provisional diagnosis of the registered eye, best corrected visual acuity of the registered eye, visual potential, presence of vascularization, type of keratoplasty and category of registration.

Results: 2115 registration forms were analyzed, out of which 59.57% were males and 40.4% were females, 5.1% were infants. Healed infectious keratitis was the most common indication for keratoplasty. Congenital Hereditary Endothelial Dystrophy (CHED) was the most common indication (33.33%) among children.

Conclusion: Keratoplasty registration forms can serve as an essential tool to identify the clinical and Clinical profile of patients awaiting keratoplasty in India. It also helps to indirectly assess the demand of the donor cornea, which is higher despite the increasing awareness of eye donation among the general population in developing countries like India. Healed infectious keratitis is the most common indication for penetrating keratoplasty in our study from North Indian population.

Blindness is a major health problem in developing countries like India. The major causes of blindness in India are cataract and glaucoma, followed by corneal blindness.¹ The global burden of blindness has been estimated to be 39 million.¹ Out of the blind in India about 6.8 million people are blind due to corneal pathology of which 1 million have bilateral blindness.² This figure

of corneal blindness is expected to increase to 10.6 million by 2020.³ According to NPCB(National Programmed for Control of Blindness) there are 120,000 blind people in India due to corneal disease and there is an additional need for 25,000 to 30,000 corneas every year.⁴

The common causes of corneal blindness in India are corneal scarring and healed keratitis, the most common indication for keratoplasty being acquired non-traumatic corneal scar.^{5,6} These pathologies require keratoplasty which can be penetrating or lamellar in nature. It has been estimated that 50% of corneal blindness is treatable.⁷ Corneal transplantation is the most common solid organ transplantation done worldwide.⁸ Cornea is one of the immunologically privileged sites in the human body thus post-keratoplasty high survival rates have been noted. This makes keratoplasty a promising and effective surgical procedure.⁹ It can be either a full thickness penetrating keratoplasty or a lamellar keratoplasty.

We hereby present a study that assesses the clinical profile of patients awaiting optical keratoplasty from a tertiary eye care hospital in northern India and compare with statistical data in different region and time periods. As there is shortage of donor corneas and with increasing expansion of the pool of patients waiting for keratoplasty an updated situational analysis helps to assess the current status.¹⁰ The practice of using registration forms is not routinely followed in many cornea services, but is expected to serve as a useful tool to facilitate situational analysis.

MATERIALS AND METHODS

A retrospective observational study was designed and data of 2115 registered patients was analyzed. The patients who were registered for keratoplasty in the National Eye Bank (NEB) from 1st August 2014 to 31st July 2015 and were

awaiting surgery in at least one eye were included. Patients whose registration data was incomplete were excluded from the study.

The registration data of the wait-listed patients was compiled after a thorough history taking and a detailed ocular examination which was conducted at our cornea clinic services. The data collected was then documented and the patients were appropriately registered based upon whether the diagnoses were consistent with indications of keratoplasty.

These registration forms were retrospectively analyzed. The variables studied include: (1) Age of onset of the pathology or age at which the insult occurred; (2) Age at which patient was registered at the eye bank ; (3) Gender of the patient; (4) Place of origin; (5) Provisional diagnosis based upon clinical evaluation and investigations ; (6) Best corrected visual acuity in both eyes; (7) Visual potential; (8) Presence of vascularization ; (9) Type of keratoplasty ; (10) Registration category.(The criteria for registering the patients for keratoplasty in our centre is presented in **Table 1**). Collected data were analyzed using SPSS software.

RESULTS

Of the 2115 proformas of the registered patients that were analyzed, 1260 (59.57%) were males and 855 (40.43%) were females (male:female-1.5:1).The mean age of the patients was 45 ± 22 years with youngest child registered

of 11 days and oldest patient being 94 years old. Out of the total analyzed 5.1% were infants. The mean visual acuity of the registered eye of the patients was 1.30 ± 0.21 log MAR. The mean intraocular pressure was 12 ± 2.2 mmHg.

Out of the total records analyzed, majority of the patients i.e. 47.16% registered under the National Eye Bank at our centre were from Delhi. This can be attributed to the fact that the tertiary eye care hospital is located in the capital city of India. The distribution of the geographic location of the patients registered is presented in **Table 2**.Of the 2115 patients, 6.7% were one eyed and 28.1% patients had bilateral corneal disease. Amongst the registered patients the most common indication for keratoplasty was healed infectious keratitis which was 31.4% of the total evaluated. The various clinical indications for which the patients were registered for keratoplasty is presented in **Table 3**.

Patients with healed infectious keratitis were further classified based upon the morphology of the sequelae on corneal examination. Leucomatous corneal opacity was seen in 20.6% cases, 6.1% had adherent leucoma and 4.7% had macula-leucomatous corneal opacity. Next more common diagnoses that were registered included pseudophakic bullous keratopathy and failed grafts. Congenital hereditary endothelial dystrophy (CHED)-2.12 % was the most common indication amongst the pediatric patients registered followed by congenital glaucoma (1.37%) - (**Table 4**).Of those 32(23.70%) were females and 103(76.29%) were males.

Table 1: Criteria for Prioritization of Indoor Patients Awaiting Keratoplasty

Registration Category	Eligibility	Order for prioritization
EMERGENCY (E)	Patients requiring emergency therapeutic keratoplasty	Emergency + children in amblyogenic group + bilateral blind
	Pediatric keratoplasty for children < 10 years	Emergency + bilateral blind
		Emergency + children in amblyogenic age group (unilateral)
		Emergency in adult(unilateral)
		Children in amblyogenic group + bilateral blind
TOP PRIORITY (TP)	Bilaterally blind patients (BCVA < 3/60 in better eye)	Bilateral blind with BCVA<3/60 in the better eye
	Patients with progressive corneal disease suitable for endothelial keratoplasty	Bilateral progressive endothelial disease suitable for endothelial keratoplasty
PRIORITY (P)	Bilateral corneal disease with better eye BCVA < 6/60	Bilateral blind
GENERAL (G)	Patients > 10 years of age with unilateral corneal blindness	Routine

Table 2: Patient Distribution

Geographic area of registered patients	Number of patients(%)
Delhi	997 (47.16)
Uttar Pradesh	596 (28.2)
Haryana	269 (12.7)
Rajasthan	109 (5.2)
Uttrakhand	52 (2.38)
Madhya Pradesh	30 (1.4)
Bihar	16 (0.76)
Punjab	15 (0.74)
Jammu & Kashmir	15 (0.74)
Orissa	4 (0.18)
Himachal Pradesh	4 (0.18)
Chattisgarh	4 (0.18)
Assam	4 (0.18)

When evaluating post-traumatic cases, chemical injury was the most common cause (1.2%) followed by operated corneal perforation (0.3%) and operated intraocular foreign body (0.3%) and thermal injury (0.28%).

Laser interferometer fringes could be appreciated by only 22% of the patients. Deep vascularization was recorded in 8.1% of the patients. Optic nerve head cupping was found in 1.8 % of the patients by ultrasonography. All these factors affect the visual outcome hence are important parameters which need to be assessed in patients awaiting keratoplasty.

Table 3: Clinical Indications of Keratoplasty among Registered patients

Indication for keratoplasty	Number of patients (%)
Healed keratitis	664 (31.4)
Pseudophakic bullous keratopathy	571 (27)
Failed graft	251 (11.9)
Pediatric pathology	135 (6.42)
Keratoconus	120 (5.7)
Aphakic bullous keratopathy	88 (4.2)
Dystrophies(stromal)	86 (4.1)
Fuchs dystrophy	69 (3.3)
Glaucoma	48 (2.2)
Trauma	44 (2.06)
Steven Johnson sundrome	7 (0.3)
Ocular surface disease	7 (0.3)
Descemetoccele	7 (0.3)
Trachoma	4 (0.18)
Salzmann and spheroidal degeneration	4 (0.18)
Staphyloma	4 (0.18)
Corneoidic scar	4 (0.18)
Operated vitrectomy	2 (0.1)

Table 4: Indications for Keratoplasty Among the Pediatric Patients Registered

Indication for keratoplasty in pediatric population	Number of patients(%)
CHED*	45 (33.33)
Congenital glaucoma	29 (21.48)
Keratomalacia	18 (13.33)
Peters anomaly	15 (11.11)
Microphthalmos	6 (4.45)
Aniridia with glaucoma	5 (3.70)
Iris cyst	4 (2.96)
Dysgenesis	4 (2.96)
Rubella syndrome	4 (2.96)
Sclerocornea	3 (2.22)
Corneal trauma	2 (1.50)

*Congenital hereditary endothelial dystrophy

Table 5: Number of Keratoplasties from Our Centre Over a Period of One Year

Type of surgery	Number of patients operated
DSAEK	91
Triple Procedure	57
Optical Penetrating Keratoplasty	278
LK(DALK+HALK+SALK)	74
TOTAL	500

Table 6: Distribution of the different types of keratoplasties planned among the registered patients

Type of surgery planned	% of patients
Penetrating keratoplasty	37.8
DSAEK	33.6
DALK	3.5
Triple procedure	12.99
Regraft	11.21
DSAEK triple	0.9

Most of the patients registered were planned for penetrating keratoplasty (62%). The distribution of the various types of keratoplasties planned among the registered patients is presented in **Table 6**.

DISCUSSION:

Corneal transplantation is the most commonly done organ transplantation procedure.¹⁰ It has been estimated that 95% of corneal blindness is avoidable.¹² The mean age of our patients was 45±22 years which were consistent with various other studies.^{11, 12}

Most of the patients registered were males and the most common indication for keratoplasty was healed keratitis (post-infectious keratitis scar) which was similar to that found in study by Dandona et al¹³ and is different from surveys of the developed nations.¹⁴⁻²⁰ Another study from Southern India²² has shown the bullous keratopathy to be the most common indication for penetrating keratoplasty which is different from our finding in Northern India. There can be various reasons for this difference including case selection, criteria for offering surgery, economic profile of the patients and local hospital policies, The high number of cases of keratitis in our country can be related to poor socio-economic conditions, lack of personal hygiene, lack of health education and delay in access to good quality health care facilities. These factors in turn emphasize the need to increase awareness about various ocular infections and their prevention and to make primary eye care accessible to all.

Failed grafts requiring re-graft were 11.21% among our patients which is comparable to the range 11.5%-17.1% reported from other parts of India^{13, 22} as well those from the developed nations.¹⁴⁻²⁰

Pseudophakic and aphakic bullous keratopathy consisted of 27% and 4.2% respectively. This is consistent with the reports from developed countries¹⁴⁻²⁰ but contrasts with the results from other studies based in India^{13, 23}. The relative increase in the percentage of pseudophakic bullous keratopathy over aphakic bullous keratopathy indicates the changing scenario of cataract surgery in India with reduced number of intracapsular cataract extraction and a shift towards extracapsular cataract extraction and phacoemulsification with intraocular lens implantation in our country. This reflects an improvement in the infrastructure, surgical techniques and the availability of trained surgeons.

Fuchs dystrophy constituted to 3.3% of patients awaiting penetrating keratoplasty which is less than that reported from developed countries ranging from 4.4% to 19.5%¹³⁻¹⁹ but comparable with that reported from India of 3.85%²³. When compared to the developed nations statistics suggest a delayed diagnosis of endothelial dystrophy in our setup. As a result there is an increased need for penetrating keratoplasty as compared to endothelial keratoplasty, which is usually the preferred surgical procedure.

Keratoconus was found in 5.7% of our patients which is higher than that found in Southern India (1.96%)²¹ but comparable with that found in other parts of India.^{23, 24}

Among the pediatric patients registered for keratoplasty, most common indication was CHED (2.12%) followed by congenital glaucoma (1.37%). The other indications for the

keratoplasty among the pediatric population is presented in **Table 4**. Keratomalacia was found only in 0.85% of our patients which was way less than that reported previously from our country.²⁵ This might be an indirect indicator of improved nutrition and immunization status in our country as compared to the scenario 20 years ago. Keratomalacia as a diagnosis itself emphasizes the need to educate the parents about the nutritional needs of a child, to practice correct breastfeeding and weaning practices, the role of immunization and dietary supplements.

When considering all these parameters we realize there are certain factors which affect the functional and anatomical outcomes after a corneal transplant. Thus these factors help to appropriately prioritize the patients on the urgency to operate. In addition, there is a need to identify the high risk cases and to adequately understand as well as explain to the patients the expected outcomes.

According to this, 62.6% were registered under top priority (TP) of which 33.6% were for DSAEK 0.9% for DSAEK triple and 28.1% were bilaterally blind. 8.3% were registered under emergency (E), 11.84% were registered under priority (P) and 17.26% were registered under general (G) category.

The number of optical keratoplasties from our centre over a period of one year is around 500 (**Table 5**). This figure is far less than the number of new cases added to the waiting list when registered for keratoplasty. The number of new patients registered for keratoplasty over a span of one year were 2227 [N=n (2115) +122(number of incomplete forms excluded from the study)] when the incomplete forms were also included. Considering the percentage of failed graft in our study, 11.9% of these patients might again be added on to the list of those awaiting keratoplasty .i.e. 1866 patients are being made to wait for their turn every year. When other factors responsible for graft failure such as deep vascularization, glaucoma, adherent leucoma would be taken into account, this number might further rise adding onto the further demand for donor corneas. This requires persistent efforts to quench the ever increasing demand of donor corneal tissues. The Hospital Cornea Retrieval Program is one such initiative which might serve the purpose.

Healed infectious keratitis still remains the most common indication for keratoplasty in Northern Indian population. Keratomalacia patients reported in our study were less than that reported in earlier studies indicating improvement in nutrition and immunization status in our country. Nevertheless, the number of pediatric female patients registered for keratoplasty was only 23.71% as compared to 76.29% of male children. This might be an indirect

indicator of the gender bias in utilization of healthcare facilities in rural India.

The modifiable indications such as healed infectious keratitis and trauma accounted for 33.46% of our patients. Studies from developed countries such as United Kingdom²⁶ reported this to be 7.2%(5.9%viral keratitis and 1.3% mechanical trauma) and that from Singapore²⁷ reported this to be 20.2% (12.9% post-infectious scarring and 7.3% post-traumatic scarring). By creating awareness regarding proper hygienic measures to prevent the occurrence of infections and trauma, the need for donor corneas can thus be reduced by a significant percentage annually.

CONCLUSION

Thus we conclude that keratoplasty registration forms can serve as an essential tool to identify the clinical profile of patients awaiting keratoplasty in India. It also helps to indirectly assess the demand of the donor cornea in our setup. Healed infectious keratitis is the most common indication for penetrating keratoplasty in our study from North Indian population.

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