Abstract

PURPOSE To evaluate the quality control of corneal tissue processed by an Eye Bank of Southern India, utilized and distributed during the year 2010.

Study Design Retrospective Observational Case series

Methods A questionnaire was mailed to every transplant center utilizing the cornea distributed by our eye bank. Similar data were also collected from our institute. Information like donors age, endothelial cell count and surgical indication were collected as well as time between death and procurement (enucleation time) and time between procurement and tissue utilization (preservation time).

Diagnosis of specific complications during postoperative period was made by reporting ophthalmologists. All the cases of early infection, endophthalmitis and primary graft failure were reported through adverse reaction reporting. Statistical Comparison was done between the groups without any early complication (group 1) and the group with early adverse reaction (group 2) at 1 month follow up.

Results: Out of total 1352 corneas retrieved during the year 2010, after quality evaluation and serological testing 376 were considered unsuitable for surgical use. Amongst the remaining 976 corneal tissues, 181 corneas was utilized in Little Flower Hospital Angamaly and 795 corneas were issued to other corneal surgeons. After attempt to congregate information regarding the distributed cornea, data of 311 corneal tissues were not available and were thus excluded from statistical analysis.

In this study there was no clear statistically significant difference between (group 1) without any complication and (group 2) early adverse reaction like primary graft failure and infection at 1 month follow up with donor age, endothelial cell count, enucleation time and preservation time.

Conclusion: In this study, we did not find any clear correlation between graft survival and primary failure or infection with various donor factors like donor’s age and endothelial count as well as time to enucleation and preservation. In this study all cases of primary failure and infection were reported for therapeutic keratoplasties utilizing large size corneal grafts.

Reporting all adverse events that might be attributable to donor eye tissue to the distributing eye bank can be helpful in order to enhance the quality control of eye bank, therefore “surveillance registry” should be made mandatory.

Keywords: Quality control, adverse event, graft survival.

Introduction

Corneal transplantation is the most commonly performed of all types of organ transplantation and is successful for visual rehabilitation of the corneal blind[1,2]. Quality control is fundamental to success of corneal transplantation.

In recent years, the number of donor corneas procured by eye banks is steadily increasing all over the world[3]. Safety and viability of the donor cornea is an essential prerequisite for successful outcome of corneal transplant procedure. The medical standards and quality control measures followed by eye banks largely determine the quality of cornea supplied for surgery.

Quality control begins with the process of selecting donor, utilization of appropriate technique for the enucleation or corneoscleral rim excision, corneal tissue preservation and evaluation of parameters such as serology of donor, count and morphology of endothelial cell. One of the main criteria for quality evaluation of corneal tissue is biomicroscopic examination performed at the slit lamp.

The purpose of this study was to evaluate the quality of corneal tissues processed and distributed by Little Flower Hospital Eye Bank in the year 2010.

Materials And Methods

A questionnaire was mailed to every transplant center utilizing the cornea distributed by our eye bank in the year 2010. Similar data were also collected from our institute by retrospective review of the charts. Information like donor’s age, endothelial count and surgical indication were collected as well as time between death and enucleation and time between enucleation and tissue utilization.

All cases of primary graft failure, which is defined as diffusely persistent corneal edema from first post operativeday which has not cleared at any point of time, for at least a period of 1 month were recorded. Similarly Cases of infection during
initial 1 month follow up period were also noted.

All corneal tissues were obtained by the eye technician in accordance with the guidelines of Eye Banking given by National Program for Control of Blindness. Donor details like cause of death, age and time since death were noted.

Disinfection and Preparation: To determine the ocular suitability of the corneoscleral rim surface, lids, adnexa and the surrounding skin were examined in situ with the penlight before excision in all cases. The eyes were removed by standard surgical procedures maintaining aseptic conditions. The area around the eyes, eyelids, nasal area and forehead were cleaned in a centrifugal manner first with alcohol pads then with betadine. Lashes and lid margins were scrubbed one time across in a circular manner with a cotton tipped applicator (CTA) dipped in 5% betadine, using separate CTA for each lids.

For globe preparation 1.5 ml of 5% betadine is filled in syringe and 2-3 drops were dripped in eye separating the upper lid using CTA and left in situ for 3-5 minutes during this period the donor is draped and sterile field is created, instruments were placed in this sterile field. After donning sterile glove the eyes were irrigated with BSS, eyes were then opened using sterile CTA and speculum was inserted.

In case of whole globe excision, with the help of the toothed forceps, the conjunctiva was grasped close to the limbus and a small cut was made in the conjunctiva with the conjunctival scissors. The scissors were introduced with their blades closed into the space between the conjunctiva and the sclera and a blunt dissection done so as to separate the conjunctiva as close to the limbus as possible. The conjunctiva was cut from the limbus 360 degrees around the cornea making two or more relaxing slits radially in the conjunctiva, so as to prevent conjunctiva from coming in the way during excision. 5 to 10 drops of antibiotic solution were on the cornea. An incision was made through the sclera using #15 sterile blade, 2 to 3 mm from the limbus, and 4 to 5 mm in length into the suprachoroidal space. Using the right and left Castroviejo corneal scissors, the sclera was cut 360 degrees evenly with the blades of the scissors. With the unused toothed forceps, the cornea was held by its scleral rim and with the iris forcefully pulled from away the iris and transferred into MK media.

Following enucleation, 5 ml of blood is withdrawn from the deceased body to check for infectious diseases. The serum from the blood of the donor is checked for HIV and Hepatitis B. Only if the serology result is negative, the donor cornea is utilized.

After excision the corneoscleral rim/eye ball was transferred to the ice box with ice packs placed inside so as to maintain a temperature of 0-40 C. The eye jars and the vacutainer containing blood was placed, between these containers of ice in a moist sponge. After reaching the eye bank the tissues are transferred to the refrigerator with temperature monitoring with additional thermometer maintaining the temperature of 0-40C. Emergency back up power was maintained.

Every corneal tissue was evaluated by means of slit lamp, with special attention on examining the surface of epithelial layers, view of stroma, degree of folds on the descement membrane and endothelial layers. The endothelial cell count and morphology was evaluated by specular microscopy –KONON. In case of whole globe excision analysis was performed in vertical laminar flow cabinet using filtered air and positive pressure. Microbiological environment controls were performed regularly on each biohazard cabinet.

Eye bank questionnaire

Confidential information
1. Surgeon name -
2. Phone no. –
3. Mail ID –

Information Regarding Cornea Received In Year 2010
4. No. of cornea received - ….
5. No. of cornea utilized - ….
6. Reason for discarding tissue ( if any ) - ….
7. Sending preservative media or residual tissue for
microbiological evaluation……..

**Adverse reaction report**

Please fill the individual details of every case of adverse reaction (if any)

(please copy and fill following section separately for every case with adverse reaction)

1. Date of diagnosis – …………
2. Postoperative day-………….
3. Graft failure (primary/secondary)……..
   - Corneal infection –
   - Endophthalmitis –
   - Others -

**Procedure performed**-

(PKP / DALK /DSEK / Scleral graft )………………..

**Others** ……………….
   - Recipient information –
     1. age ………
     2. sex
     3. Preoperative diagnosis ……….

**Donor tissue information** –

Donor ID no. – …………..

Preservation-utilization interval (hrs) – ………..

Preservation method - (Moist chamber/MK) …..

**Grading of tissue (eye bank)**

(Excellent /Very good /Good/ Fair/Poor)…………..

Change in grading of tissue according to surgeon (if any) - ……..

Statistical analysis of data is done using SPSS version.16 software. Outcomes of corneal tissue distributed by little flower hospital eye bank during 2010, at 1 month follow up was done. The variables that were compared were donor age, death to enucleation time, preservation time and endothelial count. Continuous variables were described as means and standard deviations and were compared using the independent sample test. A P value < .05 was considered to be statistically significant

**Results**

Out of total 1352 corneas retrieved during the year 2010, after quality evaluation and serological testing 376 was considered unsuitable for surgical use. Amongst 976 corneal tissues 181 corneas was utilized in Little flower hospital angamaly and 795 corneas were issued to other corneal surgeons. After attempt to congregate information regarding the distributed cornea, data of 311 corneal tissues were not available and thus excluded from statistical analysis.

**Details of the total tissues retrieved in the year 2010**

![Graph showing details of tissues utilized in 2010](image)

**Outcome of tissues utilized**

<table>
<thead>
<tr>
<th>Group</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>CLEAR</td>
<td>650</td>
</tr>
<tr>
<td>Group 2</td>
<td>EDEMA</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>INFLTRATE</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>665</td>
<td>100.0</td>
</tr>
</tbody>
</table>

**Graph showing outcome of tissue utilization**

![Graph showing outcome of tissue utilization](image)
Comparison of donor tissue variables in regards with postop outcomes

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Donor age</td>
<td>60.9 ± 16.3</td>
<td>56.7 ± 20.2</td>
<td>0.320</td>
</tr>
<tr>
<td>Mean Endothelial count</td>
<td>2258.4 ± 273.5</td>
<td>2167.3 ± 221.6</td>
<td>0.201</td>
</tr>
<tr>
<td>Mean Enucleation time</td>
<td>3.2 ± 1.2</td>
<td>3 ± 1.3</td>
<td>0.654</td>
</tr>
<tr>
<td>Mean Preservation time</td>
<td>51.2 ± 24.7</td>
<td>57.3 ± 31.8</td>
<td>0.760</td>
</tr>
</tbody>
</table>

Outcome of 1 month follow up; enucleation time and preservation time in hrs

Group 1 – corneal graft without postop complication,

Group 2 – corneal graft with early postop complication

According to the post operative outcome at 1 month follow up the cases were categorized into two groups

Group 1 having no postoperative complications and the other Group 2 having complication like primary failure or infection after one month of surgery.

The mean donor age in Group 1 was 60.93yrs with standard deviation of 16.33 yrs, and in Group 2 it was 56.67 yrs with standard deviation of 20.3 yrs. The difference was not found to be statistically significant with p value of 0.320.

The mean endothelial count in Group 1 was 2258.4 with standard deviation of 273.5, and in Group 2 it was 2167.27 with standard deviation of 221.7 though count was lower in Group 2, there was no statistically significant difference between the two groups with the p value of 0.203.

The mean duration from death to enucleation (in hrs) in Group 1 was 3.4 hrs with standard deviation of 1.2, and in Group 2 the mean was 3.0 hrs with a standard deviation of 1.3 the difference between the two is not statistically significant with p value of 0.65.

The mean preservation time in Group 1 was 51.1 hrs with standard deviation of 24.7, while in Group 2 the mean preservation time was 57.3 hrs with a standard deviation of 31.8, without any statistically significant difference between the two groups with a p value of 0.76.

Discussion

“The quality in eye banking” is the application of medical science and technology in a way that maximizes its benefits to the corneally blind without correspondingly increasing its risks. Quality assurance in eye banking promotes scientific validity of the procedures, becomes accountable for the service provided, becomes committed to human care and builds trust among public.

Eye Bank in Little Flower Hospital, the first eye bank in private sector in Kerala, functioning since 1970, has been providing quality tissues to various corneal surgeons throughout the nation. In this study we are trying to evaluate the quality assured for the same.

Primary graft failure and postoperative infection were analyzed as important functional qualities. It has been reported that the incidence of primary graft failure was about 2%. In the present study, the incidence of primary graft failure was 1.8%, which is similar as the results of various other studies.

In this study there was no clear correlation between Group 1 and Group 2 at 1 month follow up with donor age, endothelial count, time to enucleation and preservation time. The result of our study are consistent with the result of other similar studies conducted in various institutes.

Our eye bank follows strict protocol for retrieval, preservation and distribution of the tissues. The maximum enucleation time has never exceeded more than 6 hrs and maximum preservation time was 146 hrs.

On further analyzing the cases with primary graft failure and graft infection, we found out that all these cases were done for therapeutic purpose with large graft size (> 9.5mm). Thus according to our study the main contributing factor to outcome are preoperative pathology and condition of recipient eye.

Conclusion

In this study, we did not find any clear correlation between graft survival and primary failure or infection with various donor factors like donor’s age and endothelial count as well as time to enucleation and preservation. In this study all cases of primary failure and infection were reported in cases that underwent therapeutic keratoplasties utilizing large size corneal grafts.

Reporting all adverse events that might be attributable to donor eye tissue to the distributing eye bank can be helpful in order to enhance the quality control of eye bank, therefore a surveillance registry should be made mandatory.

References


Dr Aneeta Jabbar, after doing her DNB from Little Flower Eye Hospital, Angamali, went on to do a corneal fellowship at LV Prasad Eye Institute, Hyderabad. Currently, she is working as Consultant Cornea Services at Little Flower Hospital.