Extending Utilization Interval for Donor Corneas in Developing Countries

23rd June, 2012

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Outline

- Purpose
- Introduction & Background
- Aims & Objectives
- Methods
- Results
- Conclusions
- Limitations

No financial disclosures

Introduction: Corneal Preservation Media

<table>
<thead>
<tr>
<th>Media/Parameters</th>
<th>McCarney (MK)</th>
<th>Optisol GS</th>
<th>Eusol C</th>
<th>Organ Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Cornea</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Cost Per Vial</td>
<td>↓</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
</tr>
<tr>
<td>Window Period</td>
<td>72-96 Hrs</td>
<td>10-14 Days</td>
<td>10-14 Days</td>
<td>30 Days</td>
</tr>
<tr>
<td>Adoption Markets</td>
<td>Developing countries (US)</td>
<td>Developed countries (Europe)</td>
<td>Developed countries (US)</td>
<td>Developed countries (Europe)</td>
</tr>
</tbody>
</table>
Prior to the study period:
- Short term storage medium (McCarey Kaufman) used solely as the corneal preservation medium

Jan 2009 onwards:
- Additional use of Intermediate storage media (ISM) - Optisol GS/Eusol C on an "as and when required" basis
- Direct placement or subsequent transfer from MK medium carried out

Background: Practice followed

Total Eyes Received

- Whole globe enucleation
- Direct placement in ISM
- Transfer to ISM after 48 hours
- Early transfer to ISM
- In situ excision
- MK at site
- Used within 48 hrs

Purpose of the study

- To retrospectively evaluate our practice of using a combination of short term and intermediate storage media (ISM) for donor corneas at the National Eye Bank (NEB)

Objectives

- To analyze the conditions/situations that required the use of intermediate storage media
- To assess for any adverse reactions associated with the sequential use of multiple media
Method

- **Design**: Retrospective Analysis
- **Time Period**: 01-Jan-2009 to 31-Dec-2011
- **Source**: Records of the National Eye Bank (NEB), Dr. R. P. Centre for Ophthalmic Sciences, AIIMS, New Delhi
- **Subject**: All donor corneas preserved in Optisol GS/ Eusol C / Life 4C
- **Variables**: Donor Cornea Grade, Indication for longer preservation, Tissue utilization, Adverse reaction, if any

Observations and conclusions

Observations

- Total Eyes Received = 1653
- Optical Grade = 715
- Non-Optical Grade = 938
- MK Medium = 625
- Used within 48 Hrs = 566
- Direct / early placement = 22
- Late transfer to ISM = 29
- ISM (direct/ early placement) = 38
- ISM (direct/ early placement) = 15
- MK medium = 922

Observations: Indications for longer preservation

- Direct / early placement
  - Late transfer
    - OR: 28
    - GA: 24
    - OEB: 9

DRT: Death- Retrieval Time
OR: Operating Room
GA: General Anesthesia
OEB: Other eye bank transfer
Observations: Utility Profile

- Total surgeries performed: 161
- Mean age: 38.2 yrs (4m-86 yrs)
- Longevity of tissues: 73 hrs (2.5-249.7 hrs)

No of eyes:
- Used: 159
- Not used: 6

Not used:
- 4-NSFS (swab +ve/too small, from 37 wks GA premature infant)
- 2- damaged during microkeratome pass

Observations

- Majority of corneas utilized between day 3-6 day 6
- Total surgeries performed: 161
- Mean age: 38.2 yrs (4m-86 yrs)
- Longevity of tissues: 73 hrs (2.5-249.7 hrs)

Transfer related Adverse events

- Primary donor failure: None
- Graft infection: 2

Graft related adverse events

- Subsequent use of intermediate storage media: 81
- Graft infection: 2
- No Graft Infection: 72
- Direct placement into intermediate storage media (Control): 84
- Graft infection: 1
- No Graft Infection: 83
Conclusion

- Necessity for longer preservation
  - Wider window period for surgical planning and execution
  - Longer death-retrieval time necessitates waiting for culture sensitivity reports
- Sequential use of different media
  - Transfer of donor tissue from MK medium to ISM safe and effective
  - Economic and relevant use of ISM in developing nations

Limitations

- Retrospective design
- No serial tissue evaluation
- Insufficient number of cases for power analysis
- Multiple variables

Future directions

- Prospective comparative study to look for endothelial cell loss with serial specular examination in cases of transfer of cornea from MK to ISM early or after 48 hrs of preservation

Questions?
Observations: Indications for longer preservation

![Bar chart showing indications for use of intermediate storage media]

Sub analysis of eyes with DRT>12hrs

<table>
<thead>
<tr>
<th>CAUSE OF DEATH</th>
<th>No. of eyes</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARDIAC (BROUGHT DEAD)</td>
<td>4</td>
</tr>
<tr>
<td>HANGING</td>
<td>8</td>
</tr>
<tr>
<td>RTA</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>17</strong></td>
</tr>
</tbody>
</table>

- Legal considerations often lead to a delay in tissue retrieval

Adverse events: Graft infection

- 1 of 70 eyes (no transfer group)- infection
- Baseline MK data (over 3 years): no other incidence of graft infection.
- So, in effect: incidence of infection (for eyes processed at our eye bank): 1/715 = 0.13%

- **Adverse event investigation:**
  - Donor: 2 day old premature infant (developmental anomalies)
  - Sepsis screen: -ve
  - Donor cornea cultures (pre op): no growth
  - Mate cornea: optical grade, with a borderline endothelial count: 2200
  - Pre cut endothelial tissue transported to a different place for a workshop
  - Mate cornea operated for penetrating keratoplasty and did well post-operatively
  - Factors related to lamellar trephination and subsequent transport of tissue held responsible

Graft failure

- 1 eye (DSAEK)
  - Cornea: optical grade, with a borderline endothelial count: 2200
  - Used for DSAEK due to urgent need and non-availability of better quality tissue
  - Mate cornea operated for penetrating keratoplasty and did well post-operatively
  - Factors related to lamellar trephination and subsequent transport of tissue held responsible