

Corneal Explantation Activity in 2002: An Analysis of the Modified Operational Schedule

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ABSTRACT

After data have been gathered about corneal explants performed within the AOP health-care web throughout 2001, the resulting findings were used to update the selection system for donation fitness and operational procedures. The rejection of anti-HBc-positive grafts and tissues coming from subjects more than 79 years old resulted in decreased donations (256 donations, that is 492 corneal explants in 2001 vs 140, that is 273 in 2002), although the number of deaths was unchanged (1298 in 2001 vs 1294 in 2002). Corneas fit for transplantation did not change in number—126 (25.6% of the total available) in 2001 and 113 (41.4%) in 2002—while the instances of rejected corneas occurred 56.3% less frequently, allowing a savings of great deal of human and money resources. After activity schedules were modified, the results analysis confirmed the expected improvement in 2001.

ANALYSES of outcomes of corneal explants performed in 2001 and corresponding epidemiological data suggested revisions to the operational procedures for donation- and explantation-related activities.¹ Epidemiological data revealed that age at death was strongly predictive of the fitness of explanted corneal tissue in statistical terms ($P = .001$). Specifically, tissues coming from patients at or above 80 years old were only fit for transplantation in 10.5% of cases, raising major concerns about the waste of resources and about the ethical issues.

METHODS AND RESULTS

Elements of information about the in-hospital deaths throughout 2002 were reported by a dedicated database software, which allowed us to evaluate them with the highest level of specificity and viability. Thus obtained data were compared to the previous year's,² since both were collected using the same software. This database was an effective and viable means of data information collection allowing us to produce statistically correct, issue-specific reports for interpretation.

In 2001, new clinical and anamnestic criteria were introduced; namely (1), the systematic rejection of deceased patients testing positive for anti-HBc, (2) the adoption of a 79-year-old age cutoff for donation suitability, and (3) the use of a dedicated form attached to the ordinary death certificate. The adoption of new donor selection and evaluation criteria caused the number of donations to dwindle from 256 (chosen among 492 corneal explants in 2001) to 140 (from a sample of 273 corneal explants in 2002), despite the unchanged number of deaths in hospital (1298 in 2001 vs 1294 in 2002).

In 2001, 67.6% of possible donations were excluded because of

unsuitable features acknowledged on death certification forms. In 2002, the rejection rate of available corneas rose to 80.4%, due to additional information coming from the dedicated subforms.

The contacts sought among family members to assess consent to possible donation dwindled from 421 (32.4%) to 233 (18% of total decreases) within the 2 year period. Oppositions to donation expressed by family members decreased from 122 (28.9%) in 2001 to 65 (27.9%) in 2002; likewise, fewer cases were labeled as unfit for donation after family members were questioned (43 vs 28 in 2001 and 2002, respectively).

Despite the significant decrease in the number of donors and donations about the same number of corneas were fit for transplantation in 2001 (126, 25.6%) as 2002 (113, 41.4%).³

Moreover, the suitability of explanted corneal tissue was assessed by age and cause of death, separately accounting for limits to suitability, which emerged before and after the scheduled update. Unsuitability due to iatrogenic damage, which had risen up to 41.4% in 2002, sharply decreased to reach the better justifiable value of 4.8%. Likewise, unsuitability due to previous eye surgery decreased from 5.0% in 2001 to 1.5% in the following year.

Unsuitable tissue because of seropositivity increased from 9.0% in 2001 to 23.4% in 2002, an increase that was mostly due to the newly established exclusion criterion of anti-HBc positivity, which was not previously regarded as a reason for unsuitability.

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Lastly, the suitability of explants from subjects aged between 4 and 60 years increased from 49.4% in 2001, to 66.34% in 2002, while no major change was observed for the 61 to 79 age range.

CONCLUSIONS

The adoption of new criteria to select and evaluate potential donors, coupled to better corneal cryopreservation and explant techniques, allowed us to achieve objectives. Moreover, considerable, incisive changes led to improved quality and increased rate of fit corneal tissue among explants within the 2-year period (from 25.6% down to 41.4%).

This resulted in a decreased likelihood to have unfit corneal tissue explanted, thereby better addressing human resources and money supplies. On the other hand, no disadvantage as to the number of fit corneas was observed, so there was no impact on transplantation waiting lists that is approximately a 90-day wait over all Tuscany.

Eventually, the quality of corneal explants from subjects aged between 61 and 79 years (27.9% of total explants in 2001 vs 27.5% in 2002) is unlikely to be further improved through stricter selection criteria, because of age-related limits concerning "tissue stability." A further analysis of the matter is needed to assess whether there is a benefit to lower the present upper age-threshold.

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