New UNOS Allocation System and Impact upon Cardiac Transplantation

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US Heart Allocation System

• 1989: 2-tiered local + 3 zone system
  - Status 1: ICU w/inotropes, mechanical circulatory support (MCS), or IABP
  - Status 2: all others

• 1999: 3-tiered urgency-based system
  - Status 1A: Early VAD mortality 5-10%/wk
  - Status 1B: Stable on home inotropes, stable LVAD
  - Status 2: Stable at home

• 2006: integrated pediatric transplants
  - Integration of geographical proximity
  - Utilizing ABO compatibility

US Heart Allocation System

• Challenges
  - VAD morbidity/mortality evolving
  - No good predictive models for complications
  - Technology evolving, w/variable penetration
  - ECMO
  - Total Artificial Heart

• Regional variability in wait times
  - Based on Donor Service Areas (DSAs), which were defined in the 1980s
  - March 2000 HHS Final Rule: "shall not be based on the candidate’s place of residence or place of being"
  - 67% of all transplants were being performed on status 1A
  - Too many patients listed by exemption

 Wait times

• 162 percent increase in last decade
• Regional variability
  - Transplant center density
  - Population density
  - Donors and recipients
  - Cultural differences
  - Practice variability
  - Status based on treatment, not disease

• Sicker recipients
  - Older
  - Pre-sensitized
  - Retransplants

Overtreatment?

• Overtreatment defined as inotropic usage in pts absent hemodynamic criteria
• Odd of overtreatment 17.5x higher in top v. bottom quartile centers, and independent of patient factors
• Exaggerated in competitive regions (New York, Chicago, LA)
• Although trend, no better survival in higher quartile centers (p=0.08)
New UNOS Allocation System

2018 Allocation system

- Subdivides status 1A and status 1B
  - Status 1A -> status 1, 2, 3
  - Status 1B -> status 4, 5
  - Specific hemodynamic criteria defined
  - Only good for 14d
  - Renewal requires failure to wean

- Status 4
  - Hypertrophic and restrictive CMP
  - Retransplantation
  - Adult congenital heart disease

- Status 5
  - Combined organ transplant

- Mechanical circulatory support
  - VADs downgraded
  - ECMOs upgraded

- Broader organ sharing
  - Status 1 and 2 go out to Zone A (500 miles, now 250 miles)
  - Then, comes back to DSA for status 3 before going back out to Zone A

2018 Allocation system

- Pros
  - Decreases geographic disparities
  - Recognizes changes in MCS outcomes
    - 80% VAD survival at 2 years
    - No improvement in ECMO outcomes
    - No improvement in percutaneous MCS
  - Recognizes disease previously requiring exemptions
    - Hypertrophic CMP
    - Restrictive CMP
    - Retransplant
    - Adult congenital heart disease
    - VT storm
    - Multigener heart transplant

- Cons
  - Short term support devices incentivized
  - More inpatient transplants?
  - Transplanting sicker patients?
  - Bias towards HFrEF
  - Highly-sensitized patients not addressed
  - Broader sharing = longer ischemic times

Challenges

- Effects on recipients
  - 80% of transplants now on inpatients
  - Sicker recipients
- Effects on donor hearts
  - Ischemic times increased
  - More compromised donors
- Effects on transplant centers
  - Outcomes
    - “Robin Hood” effect
  - Effect on communities?
    - Fewer transplant centers?
    - Fewer candidates due to distance?
New UNOS Allocation System

Challenges

Looked at first 3 quarters since institution of new heart allocation system (Oct 2018 – Jun 2019)
90d survival rate 87.6% v. 94.5%, p<0.0001
180d survival rate 77.9% v. 93.4%, p < 0.0001
1yr hazard ratio for death or retransplantation 2.1, CI 1.5–3.0, p<0.0001

JHLT 2020;39(1):3

Challenges

1yr survival post-txp
ECMO 71.2%
p-VAD 79.9%
CF-LVAD 89.6%
No difference in acute rejection, CMV, AB

Bridging w/ECMO and P-VAD independent risk factors for 1yr mortality by multivariate analysis

Challenges

Parker. JAMA Nov 2019;332(18):1789-98
29,199 candidate between 2006—15, 68% transplanted, 27% died or re-txp
High-survival centers performed transplant on those w/lower estimated survival w/o transplant (27%) than low-survival centers (36%)
High-survival centers used 1A therapies less (35%) than low-survival centers (33%), and less likely to perform tap in those w/cardiac shock or use IAP or high-dose pressors (25% v. 31%), and less likely to use device-related complications exemption (20% v. 37%)
No significant difference in mean survival duration after transplant
New UNOS Allocation System

Meeting the challenge

- Increase donation
- Public service messages
- Donor registries
- Automated notification of OPOs
- Ongoing evolution of VAD therapy
- Approaching equipoise w/transplant
- Reassessment
- Allocation system to be reassessed
- Intermediate step towards Cardiac Allocation Score?

- TransMedics Organ Care System®
- PROCEED II Lancet Jun 2015;385(9987):2577-84
  Non-inferiority in 130 pts, 10 countries
- Donation after Circulatory Death
  Traditionally, cardiac donation after brain death
  Used in non-thoracic organs
  Ex-vivo perfusion may allow consideration
  Regulatory (Germany, US) and logistical limitations
- ABO incompatible transplants
  Precedence w/abdominal transplants
  Bergenfeldt. JHLT Jul 2015;34:892-98
  Higher 1 yr death rate, but censored survival beyond 1 yr comparable
- Hepatitis C donors
  Efficacy of direct-acting antiviral agents
  Younger donors
  Shorter waiting times (78d v. 329d)

  DONATE HCV-Trial: NEJM Apr 2019;380:3006-17
  36 lungs, 8 hearts
  Early seroconversion, but excellent graft/patient survival after DAAV x 4 wks
  4.3% v. 33% ACR, OR 0.18 (1.07-7.06)
  100% v. 83% survival, OR 0 (0.07-7.06)
  Only 1 post-transp death @ 8 mos from bacterial infection
  No adverse safety issues identified
  Shorter waiting times, shorter hospitalization vs non-HCV donors

- Dr Robert Montgomery
  Director, NYU Langone Transplant Center
  Pioneer in domino kidney transplant
  Familial CMP
  ICD @ 29 y/o
  Listed Sep 2018
  VT storm Aug 2019
  OHT 9/20/19
  4d waiting
  Back to work after 2 mos
Meeting the challenge

• Active waitlist management
  • Pre-selection committee meeting
  • Waitlist management meeting
  • Weekly Transplant Selection Committee

• All cases on support rounded on daily by interdisciplinary team
  • CV surgery, heart failure, critical care
  • Duration and complications of support continuously evaluated
  • All operative cases undergo debrief ( overseen by Quality)

• ECMO as "pop-off" valve
  • Percutaneous LVAD as bridge to recovery or bridge to transplant

Questions?

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