Establishing an Extracorporeal Photopheresis Program in Your Neighbourhood

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Disclosures

- There are no financial disclosures
- I will be discussing off label use for Therakos which is not licensed for Extra-corporeal photopheresis in Canada
- Apheresis is not an approved use for Vortex Implanted Devices
Objectives:

- Provide an overview of Extracorporeal photopheresis (ECP) in the treatment of graft–versus–host disease.
- Describe the necessary elements of a business case towards the establishment of an ECP program.
- Discuss the challenges and facilitators with the implementation of an ECP program.
- Identify vascular access options for this patient population.
Graft-versus-Host Disease

- Most significant cause of morbidity and non-relapse mortality after allogeneic hematopoietic stem cell transplantation (30 – 70%)
- Acute and Chronic forms
  - Great variability of symptoms
- Corticosteroids first line therapy
- ECP has been around for over 20 years
- Immunomodulatory therapy
- ECP has been mostly evaluated in cGVHD
How does ECP work?

- “modulation of inappropriate immune conflicts”
  - Immunosuppressive
  - Immunomodulatory
- Integrated “one step” method
- Two step method
  - Mononuclear cell collection
  - Separate UVA–irradiation
  - Re–infused to recipient
Continuous Procedure

Extracorporeal Photopheresis (ECP)

- The photoactivated white blood cells are returned to the patient
- Blood is separated by centrifugation and red blood cells are returned
- White blood cells are treated with Methoxsalen Sterile Solution and exposed to UVA light
CONTINUOUS ALLOREACTIVE T CELL DEPLETION AND REGULATORY T CELL EXPANSION FOR THE TREATMENT OF STEROID-REFRACTORY OR DEPENDENT CHRONIC GVHD - A MULTICENTER PHASE II CLINICAL TRIAL - CNTRP-1401 (THE CARE TRIAL)
Preparing Your Business Case

- **Rationale**
  - Extracorporeal Photopheresis for Second-Line Treatment of Chronic Graft-versus-Host Diseases: Results from a Health Technology Assessment in Italy*  
    - Complete and partial responses are higher with ECP than the alternative
    - Serious adverse events are less common

- **Patient safety**
  - Medical, financial and emotional burden associated with not providing the service locally

- **Resource Utilization**
  - Absorb within an established apheresis program

* Sponsored by an unconditional grant from Therakos
Preparing Your Business Case

- Capital Investment
  - Champlain Local Health Integrated Network
  - Foundation
  - Internally funded
- Operational Investment
  - Disposable costs are significant
  - Identify efficiencies
    - Apheresis very specialized
    - Highly variable volumes for acute procedures
    - Integrating scheduled ECP procedures decreases variation
  - Maintenance contract
Facilitators

- Well established BMT program with data to support proposal
  - Increasing volume of at risk patients
  - Numbers of patients affected with cGVHD
  - Complications associated with travel to receive treatment
- Supportive senior administration
- Business acumen within the program
- Outstanding Apheresis program
  - Therapeutic procedures
  - HSCT collections
Barriers

- Capital costs
- Heterogeneous group of patients
- Difficult to determine objective response
- Machine failures
- VASCULAR ACCESS
Vascular Access Options
Vascular Access Complications

- **Catheter Related Blood Stream Infection**
  - High risk patient population
  - Big catheters
  - Significant morbidity and mortality risk

- **Implanted Ports**
  - Functions well in some patients
  - Access needle (nail) 14 gauge
  - Need to assess skin tugour on chest wall
  - Rotate site
  - Once you have eschar needs to be removed
  - Dual lumen 12 French catheter
  - Single lumen 8 French
Vascular Access Approaches

- Use single needle when issues arise
  - Required blood flow rates are low and can be very low
- Use regular IVs to bleed and return into (yes 20 gauge)
- Be patient and patient-centered (faster is not necessarily better)
- Schedule procedure frequency to preserve access
- Use ultrasound to locate veins
Outcomes

- Patients tolerate procedure well
- Goal is to obtain enough product to treat and return
- Flexible procedure scheduling
  - No literature to support one schedule is better
  - Hours of operation 7 days/week
  - Patient preference
  - Preserve vascular access
- Apheresis is really about vascular access
Thank you

https://www.youtube.com/watch?time_continue=115&v=kksGYiQWo10