Maine Medical Center
Maine Transplant Program
Policies and Procedures
Hepatitis C Virus (HCV) and Kidney Transplantation

Purpose: To define:
- Pre-transplant testing of kidney transplant candidates for HCV antibody,
- HCV-positive Kidney Transplant Selection Criteria,
- Treatment options for HCV RNA-positive kidney candidates, and
- Post-transplant management of HCV RNA-positive recipients

Background
Hepatitis C is a risk factor for poor outcomes after kidney transplantation due to:
- New-onset diabetes after transplant
  - Accelerated atherosclerotic cardiovascular disease and cardiovascular mortality
- Liver failure
- Hepatocellular carcinoma
- Premature kidney allograft failure
  - Thrombotic microangiopathy
  - Immune complex glomerulonephritis

Procedures

Pre-transplant Testing
All kidney transplant candidates are screened for the presence of HCV antibody.

If positive, HCV RNA NAT is obtained
- HCV Ab +/-RNA -:
  i. Ultrasound to rule out Chronic Liver Disease/Portal hypertension
  ii. If negative, proceed with routine transplant evaluation
- HCV Ab +/-RNA +:
  i. Ultrasound to define liver/spleen anatomy and determine presence of portal hypertension
  ii. HCV Genotype analysis
  iii. Hepatology consultation
    - Liver biopsy (Mandatory)
    - Discussion about treatment options
  iv. Case discussed at Candidate Review Meeting for decision about candidacy for kidney transplantation

HCV+ Kidney Transplant Selection Criteria

Inclusion Criteria:
- Compensated liver disease
  i. Normal serum albumin
  ii. Absence of coagulopathy
  iii. Absence of portal hypertension

Exclusion criteria
- Decompensated liver disease
  iv. Encephalopathy
  v. Coagulopathy: INR>1.8
  vi. Hypocalbuminemia
- Portal Hypertension
  i. Ascites
ii. Varices
   - Advanced stage fibrosis
     - Bridging fibrosis alone may not be a contraindication to kidney transplantation as long as the
       liver disease is compensated and there is no evidence of portal hypertension

**Treatment Options for HCV RNA+ Kidney Candidates:**

1. No Treatment
2. Treatment options include various combinations of
   - Pegylated Interferon
   - Ribavirin
   - Direct Acting Antiviral (DAA) include:
     - Sofosbuvir (first line)
     - Simeprevir (first line)

For patients with preserved GFR:
   - Genotype I & IV: Rx IF/Riba/Sobosbuvir x 12 wks
   - Genotype II & III: Rx Sofosbuvir/Riba x 12-24 weeks

**Issues Pertaining to Management**

*Pretransplant:*
   - FDA advises ribavirin be used “with caution” if CrCl<50mls/min due to risk of severe hemolytic
     anemia
   - Sofosbuvir “No dosing recommendation for ESRD or Clcrea<30mls/min”
   - There is no regimen that has a proven safety/efficacy profile in patients for CKD IV or ESRD.

*Kidney Choice:*
   - HCV+ Patients will be offered the opportunity to receive a HCV+ allograft.
   - This may reduce the expected waiting time.
   - This may expose the patient to risk of a HCV with a different genotype.

*Post transplant:*
   - Interferon contraindicated due to risk of rejection
   - Protease inhibitors (Simepravir, telaprevir and bocepravir) are profound inhibitors of CYP450 3A/4
     thus risk of CI toxicity and are best avoided after transplantation
   - Sofosbuvir is not a PI, is not a CYP3A/4 inhibitor and has no PK interactions with
     immunosuppression
   - Sofosbuvir/Ribavirin without IFN are Rx of choice for transplant recipients assuming GFR is
     adequate
   - All HCV viremic patients will be referred to Hepatology for opinion on post transplant management

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