Society of Thoracic Surgeons

Intermacs Updated Adverse Events Webinar

November 16, 2021

STS National Database™
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- Welcome and Introductions
- STS Updates
- Updated Adverse Events Overview

The Intermacs Data Warehouse Team

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Database Operational Questions

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Resources

- STS National Database Webpage
- Intermacs and Pedimacs Webpage (All things Intermacs and Pedimacs, Database user guides, Data collection forms, QOL surveys, FAQs, V 6 Training Video, Research opportunities)
- Intermacs-reports@uabmc.edu (Reporting questions, Uploader, DQR, Missing Variable, Dashboard, Password and Login)
- Updated Participant Contact Form
- DQ Report Validation Form

Upcoming Intermacs Webinars

Dashboard Analytics

- December -TBD

Quarterly Reporting Webinar

- January 20, 2022 @ 2:00 pm CT

Open Discussion

Please use the Q&A Function.

We will answer as many questions as possible.

We encourage your feedback and want to hear from you!

Updated Adverse Events Overview

Kathryn A. Hollifield, BSN, RN

STS National Database Manager-Intermacs & Pedimacs

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Major Adverse Events

- Major Infection
- Major Bleeding
- Neurological Dysfunction
- Device Malfunction/Device Failure

Additional Adverse Events…

- Hemolysis
- Right Heart Failure
- Renal Dysfunction

Major Infection

- Two Categories:
  - MCS Related
  - Examples: Percutaneous lead site infections, Infection of external surfaces of an implantable component(infected tissue surrounding the external house component) and device endocarditis.
  - Non-MCS Related
  - Examples: Blood stream infections, Sepsis, localized non-mcs device infection (pneumonia, urinary tract infection)

Major Bleeding

- Updated to Types (1-5)

- Type 1: Bleeding that is NOT actionable and does NOT cause the patient to seek unscheduled performance of studies, hospitalization, or treatment by a healthcare professional (Common nose -bleed)

Major Bleeding Type 2:

- Type 2: An overt, actionable sign of hemorrhage (e.g., more bleeding than would be expected for a clinical circumstance, including bleeding found by imaging alone) that does fit criteria for Type 3, 4 or 5 but does meet at least one of the following criteria:
- Requiring non-surgical, medical intervention by a healthcare professional;
- Leading to hospitalization or increased level of care; or
- prompting evaluation

Major Bleeding Type 3

- Type 3
  - 3a Overt bleeding accompanied by Hgb drop of 3 to less than 5 g/dl
  - The Hgb drop must be related to the bleeding event
  - 3b Overt bleeding accompanied by a Hgb drop of 5 g/dl or greater, the Hgb drop must be related to the bleeding event
    - Cardiac Tamponade
    - Bleeding requiring surgical intervention for control(excluding dental, nasal, skin and hemorrhoids)
    - Bleeding requiring IV vasoactive agents

Major Bleeding : Type 4

- Type 4
  - VAD implanted related bleeding
    - Reoperation after the closure of incision or incisions used to implant the VAD to control the bleeding
    - > 50 kg: >4U PRBC within any 48 hours during the first 7 days post-implant
    - Chest Tube output greater than 2 liters within 24 hours

Major Bleeding : Type 5

- Fatal Bleeding

- 5 a: Probable fatal bleeding; no autopsy or imaging confirmation but clinically suspicious

- 5b: Definite Fatal bleeding; confirmation

Neurological Dysfunction

- Types 1-3
- Type 1: Overt CNS Injury; acutely symptomatic brain or spinal cord injury
- Strokes, Ischemic Stroke with Hemorrhage,
- Type 2: Covert CNS Injury; acutely asymptomatic brain or spinal cord injury detected by neuroimaging
- Type 3: Neurological Dysfunction , acutely symptomatic without CNS injury
  - TIA, Delirium

Device Malfunction

- Major Device Malfunction
- Minor Device Malfunction
  - NOTE: Replacement of external controller that is done in an inpatient setting for logistical reasons, in an otherwise stable patient, should be considered a minor device malfunction rather than major

Hemolysis

- Now an entered event…..
- Major Hemolysis
- Minor Hemolysis

Major Hemolysis

- A plasma-free hgb value greater than 20 mg/dl or a serum LDH level greater than 2.5X the upper limits of the normal range at the implanting site occurring AFTER the first 72 hours post-implant and associated with clinical symptoms or findings of hemolysis or pump malfunction

Minor Hemolysis

- A plasma-free hgb value greater than 20 mg/dl or a serum LDH level greater than 2.5X the upper limits of the normal range at the implanting site occurring AFTER the first 72 hours post-implant in the absence of clinical symptoms or findings of hemolysis or pump malfunction

Right Heart Failure

- Early Acute Right Heart Failure
- Early Post-Implant Right Heart Failure
- Late Right Heart Failure

Early Acute Right Heart Failure

- Need for implantation of a temporary or durable RVAD (including ECMO) concomitant with LVAD implantation; RVAD implanted before the patient leaves the operating room

Early Post Implant Right Heart Failure

- Need for implantation of a temporary or durable RVAD(including ECMO) within 30 days following LVAD implantation for any duration or,

- Failure to wean from inotropic or vasopressor support or inhaled nitric oxide w/in 14 days following LVAD implantation or having to initiate support w/in 30 days.

- Must have 2 clinical findings and 1 manifestation from the criteria listed on the RHF form

Late Right Heart Failure

- RVAD implantation (including ECMO) greater than 30 days after an LVAD implant. This may occur within the index hospitalization for LVAD implant or during subsequent rehospitalization for any diagnosis which resulted in a need for temporary or permanent right sided mechanical device assist devices

- Hospitalization that occurs >30 days post-implant and which requires IV diuretics or inotropic support for at least 72 hours and is associated with 2 clinical findings and 1 manifestations

Late Right Heart Failure Clinical Findings

- Must have 2 of the following clinical findings:
  - Ascites
  - Functional limiting peripheral edema (>2+)
  - Elevated estimated JVP at least halfway up the neck in an upright patient
  - Elevated CVP(>16 mm Hg)

Late RHF Manifestations

- Must Have One Manifestation:
  - Renal serum creatine >2 baseline
  - Liver Injury with an elevation of at least 2x upper limit normal AST/ALT or Total Bili >2.0
  - Pump Flow reduction >30% from previous baseline in the absence of tamponade
  - SVO2<50%
  - Cardiac Index <2.2 liter/min/m2
  - Elevated lactate >3.0 mmol/liter

Renal Dysfunction

Acute v Chronic

- Acute: 3 stages
  - Vary in serum creatine levels and urine output
  - Stage 3 : Renal Replacement Therapy (includes dialysis or ultrafiltration)

- Chronic: Increase in serum creatinine of 2 mg/dl or greater above baseline or requirement for renal replacement , either of which is sustained for at least 90 days

Association Classification

- Patient-Related: Non- adherence to medical therapy
- Management related: Medication management or medical treatment related issues
- Device related: Device issue resulting in adverse event

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THANK YOU FOR JOINING!