REBOA Can Save Lives But...

When can REBOA cause spinal cord ischemia and can balloon deflation prevent it

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Disclosures

- Medical Advisory Board Member Prytime Medical Devices Inc.
- Royalty Distributions and Stock Options

Background

- REBOA utilization for trauma and hemorrhagic shock has increased greatly over the last decade
- Comparative data with resuscitative thoracotomy is favorable
- Case series and some meta-analyses suggest a clinical benefit

Spinal Cord Injury

- Surgical cross-clamp of the aorta has long been associated with spinal cord ischemia risk
- In open repair of BTAI historic rates of paralysis with no distal perfusion adjunct was 19%
- Prolonged REBOA is associated with SCI in porcine model
- Prolonged REBOA is associated with SCI rarely in humans (7 high mortality in this population)

Nonhuman Primate Studies - Advantages

- Advantage of studying defined times for REBOA
- Bipedal model with spinal cord anatomy analogous to humans
- Coagulation cascade identical to humans
- Can prospectively evaluate neurological function and histology

Background

- An ideal time for balloon occlusion is not clear
- Many reports do not record balloon occlusion times
- Animal studies suggest morbidity and mortality end-points are increased with 60- and 90-minute occlusion times
- In human studies, when balloon occlusion times have been compared, they are shorter in survivors than in patients who died
Nonhuman Primate Studies

- All animals in the 60-minute REBOA group had histological evidence of renal parenchymal injury.
- 13% of animals in the 60-minute group had elevated Troponin I and histological evidence of myocardial infarction.
- 50% of animals in the 60-minute REBOA group had paralysis and histological evidence of spinal cord injury.
Nonhuman Primate Studies – 60 Minute REBOA

Arrows = cavitation in the latero-ventral horns (arrows) and Macrophage Infiltrates
Arrowhead = Necrotic neuron with hypereosinophilia

Nonhuman Primate Studies – 60 Minute REBOA

Arrows = ischemic injury to the dorsal horn and dorsal column with neuronal loss and inflammatory cell infiltrates
6E and 6F shows a normal spinal cord section at low and high magnification for comparison

Nonhuman Primate Studies - Summary

- 60-minutes of REBOA balloon inflation after profound hemorrhagic shock in the nonhuman primate is:
  - Life Saving (93% survival in this study)
  - Morbid
    - 50% Spinal Cord Ischemia
    - Metabolic Derangement
    - Myocardial Strain/Injury
    - Renal Injury (Histological)

Nonhuman Primate Studies - Recommendations

- In this study all spinal cord morbidity was mitigated by limiting REBOA to 30 minutes
- We recommend that Zone I REBOA be limited to 30-minutes in humans
- After 30 minutes every effort should be made to only have intermittent balloon inflation to allow reperfusion to occur