TORAYMYXIN®

SHORT GUIDE TO SELECTION OF PATIENTS WITH SEPTIC SHOCK OF ABDOMINAL ORIGIN

PRE-REQUISITES

1. Adequate surgical and/or medical control of septic source
2. Early treatment according to Surviving Sepsis Campaign guidelines
   - ✓ Early antibiotic administration + blood cultures
   - ✓ Adequate fluid resuscitation and optimization
   - ✓ Early administration of vasopressors to control hypotension

DIAGNOSIS OF REFRACTORY SEPTIC SHOCK[1]

(Severe Hypotension requiring vasopressor support NEP/EPI ≥0.25 µg/Kg/min or DOPA ≥15 µg/Kg/min, despite adequate fluid replacement)

CONVENTIONAL TREATMENT AND MONITORING[2]

Corticosteroids, Hemoglobin control, Glucose control, Renal Replacement therapy, Bicarbonate therapy, Deep Vein Thrombosis Prophylaxis, Stress Ulcer Prophylaxis, Nutrition)

NEP/EPI <0.25 µg/Kg/min or DOPA <15 µg/Kg/min

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CONVENTIONAL TREATMENT AND MONITORING

+

TORAYMYXIN®

(To be performed within T24h)

+

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(To be performed within T48h)

1) Annane D et al. Lancet 2005; 365: 63-78 2) Dellinger S et al. Crit Care Med 2013; 41:580–637

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Stage	Definition (modified by Annane D et al. Lancet 2005; 365: 63-78)
SIRS	Two or more of the following criteria: • Body temperature >38.5°C or <35.0°C • Heart rate >90 beats/minute • Respiratory rate >20 breaths/minute • $PaCO_2$ <32 mmHg (4.27 kPa) or mechanical ventilation • White blood cell count >12,000/mm^3 or <4,000/mm^3 or immature forms >10%
Sepsis	SIRS and documented infection (culture or gram stain of blood, sputum, urine, or normally sterile body fluid positive for pathogenic microorganism; or focus of infection identified by visual inspection, e.g., ruptured bowel with free air or bowel contents found in abdomen at surgery, wound with purulent Discharge)
Severe sepsis	Sepsis and at least one sign of organ hypoperfusion or organ dysfunction: • Urinary output <0.5 mL/Kg for at least 1 hour or renal replacement therapy • Lactates >2 mmol/L • Abrupt change in mental status or abnormal electroencephalogram • Platelet count <100,000 cells/mm^3 or disseminated intravascular coagulation • Cardiac dysfunction (echocardiography) • Acute lung injury with PaO_2/FiO_2 <250 in absence of pneumonia as infection source • Acute lung injury with PaO_2/FiO_2 <200 in presence of pneumonia as infection source • Creatinine >2 mg/dL (176.8 µmol/L) • Bilirubin >2 mg/dL (34.2 µmol/L)
Septic shock	Severe sepsis and one of: • Systemic mean blood pressure <60 mmHg (<80 mmHg if previous hypertension) despite fluid resuscitation, or pulmonary capillary wedge pressure 12-20 mmHg • Need for dopamine >5 µg/Kg/min or norepinephrine/epinephrine <0.25 µg/Kg/min to maintain mean blood pressure above 60 mmHg (80 mmHg if previous Hypertension)
Refractory septic shock	Need for dopamine ≥15 µg/Kg/min or norepinephrine/epinephrine ≥0.25 µg/Kg/min to maintain mean blood pressure above 60 mmHg (80 mmHg if previous Hypertension)

Management of preparation and anti-coagulation of Toraymyxin treatment	
Preparation	• Fill the arterial line of the blood circuit by saline solution, completely purging air bubbles, before connecting the cartridge • Saline solution: at least 4 Liters • Heparinized saline solution: at least 500 mL/2,000UI • Saline solution (for blood return): about 500 mL
Anti-coagulation (Heparin)	• Bolus 3,000 UI + continuous infusion 20 UI/Kg body weight/h (the maximum admitted dose of continuous infusion for each patient is 2,000 UI/h) • Keep ACT or PTT values within 150-180 sec or 50-60 sec range, considering a maximum value of 240 sec and 100 sec, respectively • Consider to monitor and to supplement anti-thrombin III The recommended doses of heparin ACT or PTT values are general recommendations. The prescription of the exact dosage, the rate and mode of infusion are under the exclusive responsibility of the attending physician who should indicate them according to clinical conditions of patients. Note: Information here reported DO NOT replace a careful reading of the instruction for use accompanying Toraymyxin® device.