Perioperative Care

Greig McCreery, PGY 5

Dr. Tina Mele

Wednesday, November 18, 2015

Schulich MEDICINE & DENTISTRY

The Division Of General Surgery

University of Western Ontario

Outline

- VTE Prophylaxis
- Novel Anticoagulant review
- Elective Surgery Post PCI
- Perioperative Arrhythmias
- Sepsis
- Perioperative Antibiotic Prophylaxis
- TPN Basics – Dr. Mele

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Peri-operative DVT Prophylaxis

- The Problem
  - DVT and PE are the most common preventable causes of in-hospital death
- The Sequelae of DVTs:
  - (Massive) Pulmonary Embolism
  - Post-Thrombotic Syndrome
  - Pulmonary Hypertension

DVT Risk Factors

- Surgical patients satisfy the Virchow's Triad
  - Stasis (immobilization)
  - Endothelial injury (tissue trauma, central line access)
  - Hypercoagulable (Tissue Factor release, Malignancy, inlammatory states (sepsis), etc)

DVT Risk Factors

- Antiphospholipid, anticardiolipin antibodies
- Antithrombin III deficiency
- Protein C/S deficiency
- **Factor V Leiden**
- Prothrombin gene mutations
- Blood group non-O
- Dysfibrinogenemia
- Dysplasminogenemia
- Hyperhomocystinemia
- Reduced heparin cofactor II activity
- Elevated levels of clotting factors (XI, IX, VII, VIII, X, II)
- Elevated levels of PAI-1

DVT Risk Factors – Hematologic Syndromes

- HITT
- DIC
- Anti-phospholipid antibody syndrome
- TTP
- HUS
- Myeloproliferative Disorders

DVT Prophylaxis in General Surgery

- Fatal PE in General Surgery Patients **~0.1 – 0.8%** without VTE prophylaxis
- UFH reduces the risk of *fatal* PE by **~66%**
- LMWH reduces symptomatic VTE by **80%** in patients undergoing abdominal surgery

DVT Prophylaxis in General Surgery

- VTE Prophylaxis
  - Early ambulation
  - Mechanical
  - Pharmacologic

- Modality of depends on calculated VTE and risk of bleeding complication

- VTE risk can be calculated from evidence-bases, validated scoring systems

  - **Caprini**
  - Rogers

VTE Prophylaxis

CHEST Supplement

ANTITHROMBOTIC THERAPY AND PREVENTION OF THROMBOSIS, 9TH ED: ACCP GUIDELINES

Executive Summary

Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines

*Gordon H. Guyatt, MD, FCCP; Elie A. Akl, MD, PhD, MPH; Mark Crowther, MD; David D. Gutterman, MD, FCCP; Holger J. Schünemann, MD, PhD, FCCP; for the American College of Chest Physicians Antithrombotic Therapy and Prevention of Thrombosis Panel**

VTE Prophylaxis

Modified Caprini risk assessment model for VTE in general surgical patients

Risk score			
1 point	**2 points**	**3 points**	**5 points**
Age 41 to 60 years	Age 61 to 74 years	Age ≥75 years	Stroke (<1 month)
Minor surgery	Arthroscopic surgery	History of VTE	Elective arthroplasty
BMI >25 kg/m^2	Major open surgery (>45 minutes)	Family history of VTE	Hip, pelvis, or leg fracture
Swollen legs	Laparoscopic surgery (>45 minutes)	Factor V Leiden	Acute spinal cord injury (<1 month)
Varicose veins	Malignancy	Prothrombin 20210A	
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Abnormal pulmonary function			
Acute myocardial infarction			
Congestive heart failure (<1 month)			
History of inflammatory bowel disease			
Medical patient at bed rest			

Interpretation		
Surgical risk category*	**Score**	**Estimated VTE risk in the absence of pharmacologic or mechanical prophylaxis (percent)**
Very low (see text for definition)	0	<0.5
Low	1 to 2	1.5
Moderate	3 to 4	3.0
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VTE: venous thromboembolism; BMI: body mass index.
* This table is applicable only to general, abdominal-pelvic, bariatric, vascular, and plastic and reconstructive surgery. See text for other types of surgery (eg, cancer surgery).

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VTE Prophylaxis

VTE Risk	Bleeding Risk	Prophylaxis
<0.5%, Caprini 0 “Very Low Risk”	Any	None
<1.5%, Caprini 1-2 “Low Risk”	Any	Mechanical
<3.0%, Caprini 3 – 4 “Moderate Risk”	Low risk High risk	Mechanical ***or*** LMWH Mechanical
~6%, Caprini > 5 “High Risk”	Low Risk High Risk	LMWH ***and*** Mechanical Mechanical

VTE Prophylaxis

- **2012 CHEST Guideines**
  - "In general and abdomino-pelvic surgery patients, we suggest that ICV filter should not be used for primary prophylaxis"

VTE Prophylaxis – BPIGS

- **Low Risk Patients = No VTE prophylaxis required**
  - Outpatient surgery
  - Minor procedure (anorectal, inguinal hernia, elective lap chole, breast surgery
  - No additional VTE risk factors

- ***All other* patients**
  - Enoxaparin or Fragmin
  - If high bleeding risk or contraindication: SCDs

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VTE Prophylaxis Quiz

- Case 1
  - 32yoF (0 pts)
  - Biliary Colic
  - Overweight (BMI 29), Otherwise heathy (1 pt)
  - Meds: OCP (1 pt)
  - Lap Chole (1pt)

  - VTE Prophylaxis?
    - Caprini = 3
    - **Mechanical or Pharmacologic**

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VTE Prophylaxis Quiz

- Case 2
  - 25yoM (0 pts)
  - Acute appendicitis
  - Lap appendectomy (1 pt)
  - Otherwise heathy

  - VTE Prophylaxis?
    - Caprini = 1
    - **Mechanical**

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VTE Prophylaxis Quiz

- Case 3
  - 62yoM (2 pts)
  - Ascending Colon AdenoCa (2pts)
  - Lap Rt Hemi (2 pts)
  - Otherwise heathy

  - VTE Prophylaxis?
    - Caprini = 6
    - **Mechanical & Pharmacologic**

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VTE Prophylaxis

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VTE Prophylaxis Quiz

- Case 4
  - 45yoM (1 pt)
  - Right Inguinal Hernia Repair (1 pt)
  - Otherwise heathy

  - VTE Prophylaxis?
    - Caprini = 2
    - **Mechanical**

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VTE Prophylaxis – Extended Prophylaxis

For high-VTE-risk patients undergoing abdominal or pelvic surgery for cancer who are not otherwise at high risk for major bleeding complications, we recommend extended-duration pharmacologic prophylaxis (4 weeks) with LMWH over limited-duration prophylaxis (Grade 1B)

Many VTE events occur after discharge, with rates of 15%-40% with a **91% risk reduction in postoperative VTE**.

VTE Prophylaxis Quiz

- Case 5
  - 62yoM (2 pts)
  - Ascending Colon AdenoCa (2pts)
  - Lap Rt Hemi (2 pts)
  - Otherwise heathy

  - VTE Prophylaxis?
    - Caprini = 6
    - Mechanical & Pharmacologic

  - **When should VTE prophylaxis be discontinued?**
    - **4 weeks after discharge**

VTE Prophylaxis – Bridging Anticoagulation

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VTE Prophylaxis – Bridging Anticoagulation

- Case
  - 65yoF (2 pts)
  - Resection-rectopexy for rectal prolapse (2 pts)
  - HTN, Mitral stenosis (Rheumatic fever) (0 pts)
  - Afib, on Warfarin (0 pts)

What anticoagulation bridging is required?

- Caprini = 4
- **Low Risk for VTE**
- **No bridging required**

VTE Prophylaxis – Perioperative Bridging

- **Patients at High risk for VTE**
  - Caprini ≥ 5
  - In patients with a mechanical heart valve, atrial fibrillation, or VTE at high risk for thromboembolism, **we suggest bridging anticoagulation** during interruption of VKA therapy (Grade 2C)

- **Pt with low risk for VTE**
  - Caprini < 5
  - In patients with a mechanical heart valve, atrial fibrillation, or VTE at low risk for thromboembolism, **we suggest no bridging** during interruption of VKA therapy (Grade 2C)

VTE Prophylaxis – Perioperative Bridging

- Bridging anticoagulation with therapeutic-dose IV UFH
  - stop 4 to 6 h before surgery
- Bridging anticoagulation with therapeutic-dose SC LMWH
  - stop 24 h before surgery
- Restart at 24 hours post-op, unless high bleeding risk
- Patient not receiving pre-operative bridging (low VTE risk) should have full dose anticoagulation restarted at 24hrs post-op

VTE Prophylaxis – Perioperative Bridging

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

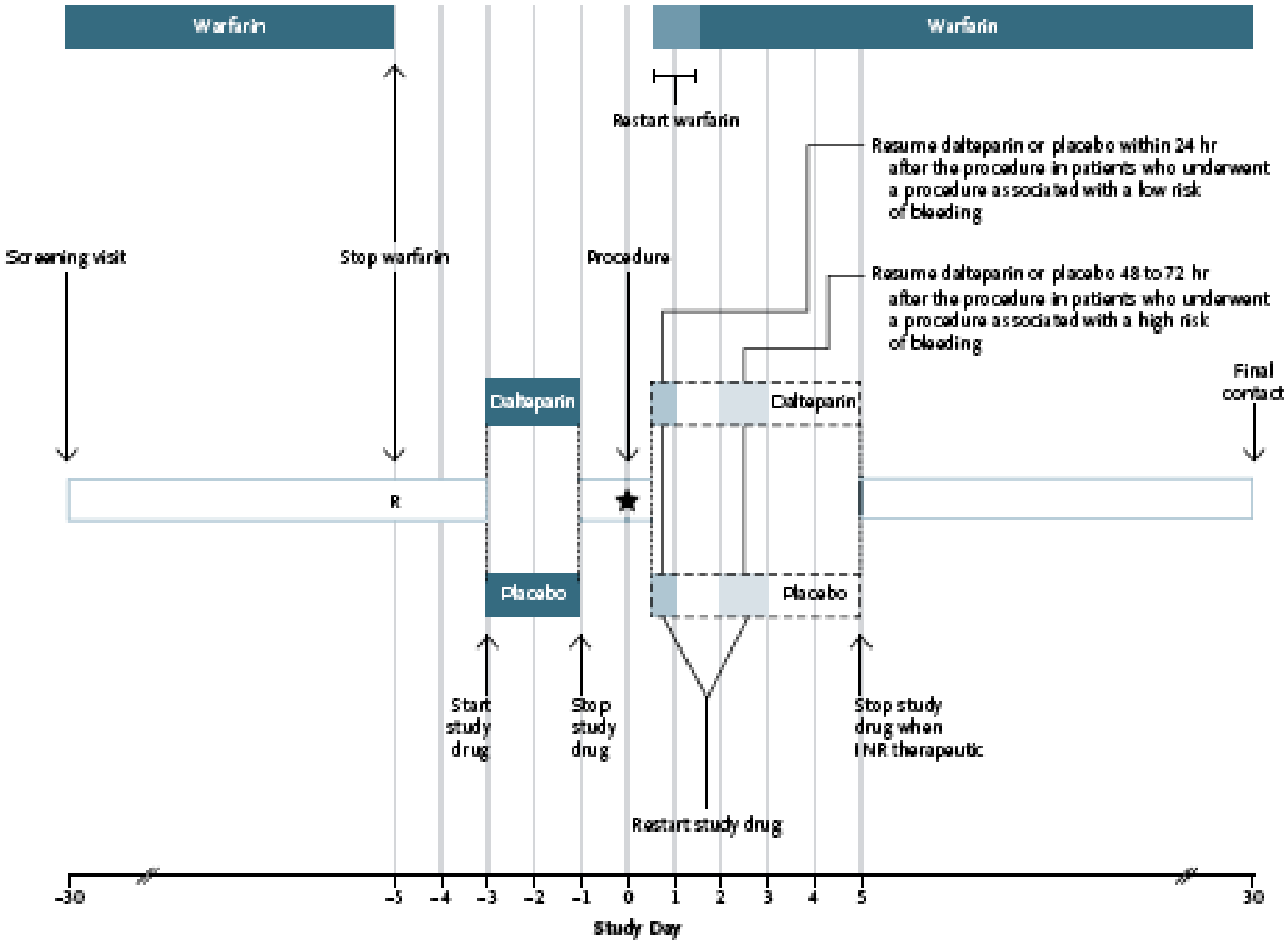
Perioperative Bridging Anticoagulation in Patients with Atrial Fibrillation

James D. Douketis, M.D., Alex C. Spyropoulos, M.D., Scott Kaatz, D.O., Richard C. Becker, M.D., Joseph A. Caprini, M.D., Andrew S. Dunn, M.D., David A. Garcia, M.D., Alan Jacobson, M.D., Amir K. Jaffer, M.D., M.B.A., David F. Kong, M.D., Sam Schulman, M.D., Ph.D., Alexander G.G. Turpie, M.B., Vic Hasselblad, Ph.D., and Thomas L. Ortel, M.D., Ph.D., for the BRIDGE Investigators*

VTE Prophylaxis – Perioperative Bridging

- **Inclusion:**
  - chronic afib/flutter
  - Warfarin > 3 months
  - CHADS score of 1 or more
- **Excluded**
  - Mechanical valve
  - Stroke
  - Systemic embolism or TIA within previous 12 weeks
  - Major bleeding in previous 6 weeks
  - CrCl < 30
  - Plt < 100
  - Intracranial, spinal or cardiac surgery
- **1884 patients**

VTE Prophylaxis – Perioperative Bridging



VTE Prophylaxis – Perioperative Bridging

Table 3. Study Outcomes.

Outcome	No Bridging (N=918)	Bridging (N=895)	P Value
	number of patients (percent)		
Primary			
Arterial thromboembolism	4 (0.4)	3 (0.3)	0.01*, 0.73†
Stroke	2 (0.2)	3 (0.3)	
Transient ischemic attack	2 (0.2)	0	
Systemic embolism	0	0	
Major bleeding	12 (1.3)	29 (3.2)	0.005†
Secondary			
Death	5 (0.5)	4 (0.4)	0.88†
Myocardial infarction	7 (0.8)	14 (1.6)	0.10†
Deep-vein thrombosis	0	1 (0.1)	0.25†
Pulmonary embolism	0	1 (0.1)	0.25†
Minor bleeding	110 (12.0)	187 (20.9)	<0.001†

* P value for noninferiority.
† P value for superiority.

IVC Filters

IVC Filters

- Indications for IVC Filters
  - Contraindication to AC
  - Complication of AC
  - Failure of AC

  - Very high VTE risk patient with a significant bleeding risk can be considered for temporary IVC filter
  - Little evidence for perioperative indications.
  - Must remember to remove filter when AC restarted.

IVC Filters

- IVC Filter in acute proximal leg DVT
  - **2012 CHEST Guideline**
    - In acute, proximal DVT with contraindication to anticoagulation, recommend use of an IVC filter. (Grade 1B)

- IVC Filter in PE
  - **2012 CHEST Guideline**
    - In acute PE and contraindication to anticoagulation, we recommend the use of an IVC filter. (Grade 1B)

Pulmonary Embolism

- **Acute ‘massive” PE an accepted indication for systemic thombolysis**
  - “massive’ = persistent hypotension or shock
    - bBP <90 or >40mmHg drop
- Compared to AC alone
  - Morality 9% vs 19%
  - Bleeding 21% vs 12%
- Catheter directed Thrombolysis (CDT)
  - Minimal evidence, **not standard of care**
  - May be considered in the early post-operative period
  - ULTIMA Trial
    - CDT for sub-massive PE demonstrated no major bleeding complications

Novel Anticoagulants

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Novel Anticoagulants

- **Dabigatran – Pradaxa (factor IIa)**
  - Afib
  - VTE Treatment in pts treated with another AC x 5-10 days
- **Rivaroxaban – Xarelto (factor Xa)**
  - VTE prophylaxis TKA & THA
  - Afib
  - VTE Treatment
- **Apixaban – Eliquis (factor Xa)**
  - Afib
  - VTE Treatment
  - Post-op Ortho prophylaxis

Novel Anticoagulants

- **Rivaroxaban – Xarelto (factor Xa)**
  - Einstein trial: **non-inferior to Warfarin**, no increased bleeding
    - Long term, no increased bleeding compared to **placebo!**
- **Apixaban – Eliquis (factor Xa)**
  - **Lowest bleeding risk compared to Warfarin**

Novel Anticoagulants – Monitoring

- **Dabigatran (factor IIa)**
  - Hemoclot assay
- **Rivaroxaban (factor Xa)**
  - Anti-Factor X level
- **Apixaban (factor Xa)**
  - Anti-Factor X level
- **$T_{1/2}$** ~ 12 hours for all NOACs

Novel Anticoagulants – Reversal

- Dabigatran (factor IIa)
  - **Dialysis**
  - **Activated PCC** (FIEBA, **VIIa**, IIa , Ixa and Xa – hemophilia tx)
  - Idarucizumab (aDabi-Fab) – ongoing human trials
- Rivaroxaban (factor Xa)
  - **4 factor PCC (Octaplex) – no human evidence**
  - Andexanet alfa – ongoing human trials
- Apixaban (factor Xa)
  - **4 factor PCC (Octaplex)**
  - Andexanet alfa – ongoing human trials

Elective Surgery Following PCI

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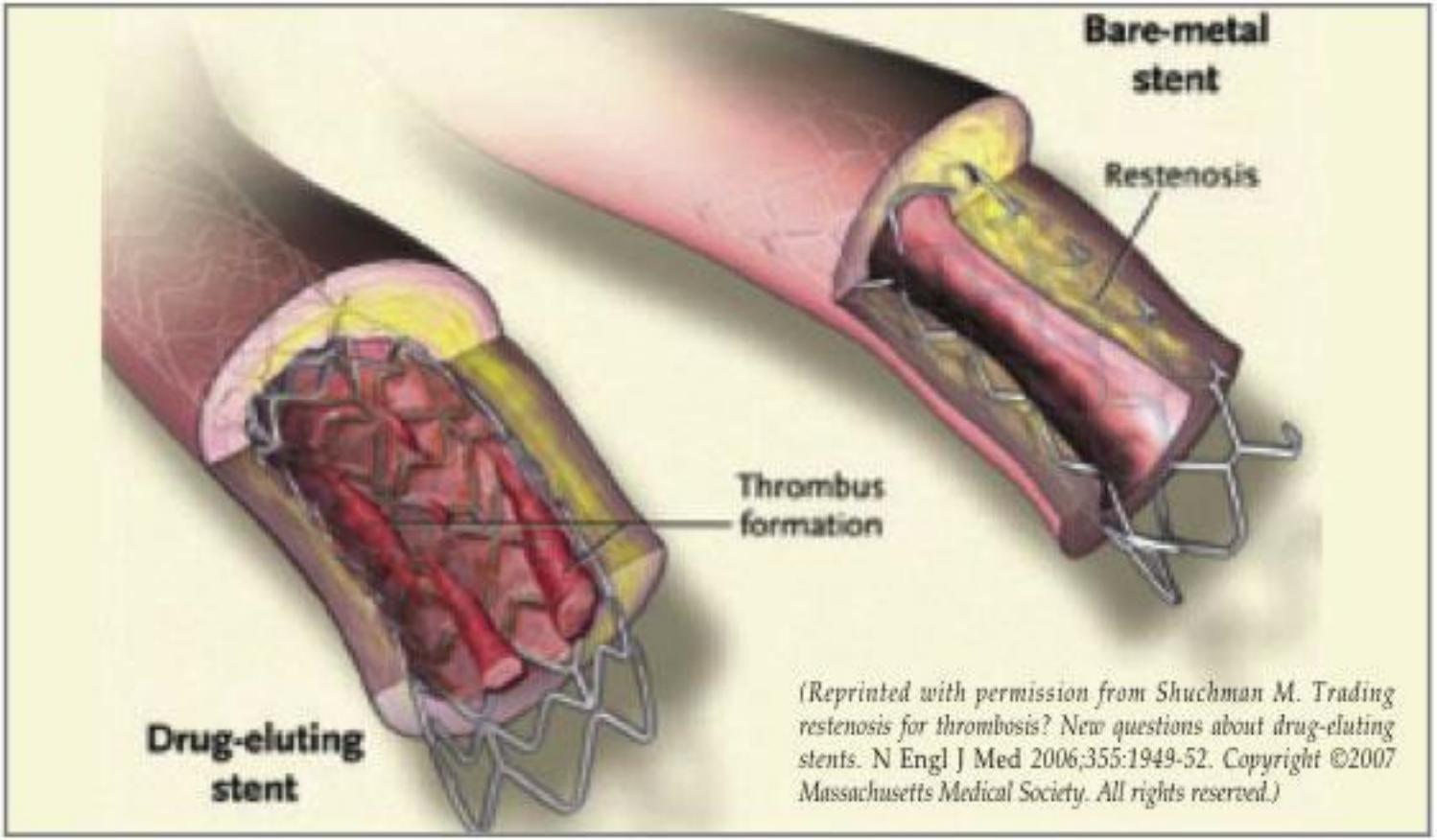
Elective Surgery Following PCI



Drawing of intraluminal view of bare-metal stent compared to drug-eluting stent.

Elective Surgery Following PCI

CLINICAL PRACTICE GUIDELINE

2014 ACC/AHA Guideline on Perioperative Cardiovascular Evaluation and Management of Patients Undergoing Noncardiac Surgery

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

Developed in Collaboration With the American College of Surgeons, American Society of Anesthesiologists, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Anesthesiologists, and Society of Vascular Medicine

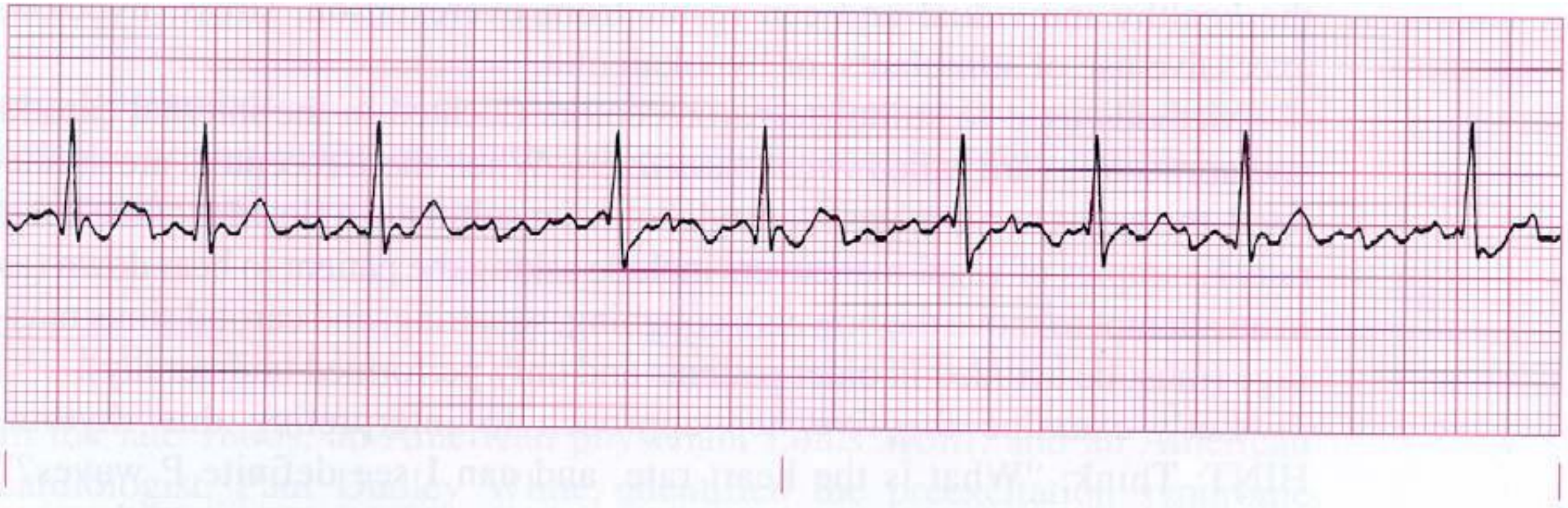
Endorsed by the Society of Hospital Medicine

Elective Surgery Following PCI

- **Drug Eluting Stents (DES)**
  - Optimally delay noncardiac surgery 365 days
  - May be considered at 180 days if high risk from delay in surgery
    - Dual antiplatelet therapy should be continued

- **Bare Metal Stent (BMS)**
  - Elective noncardiac surgery should not be preformed within 30 days
  - (**2012 CHEST Guidelines** support elective surgery being delayed 6 weeks following BMS insertion)

Perioperative Arrythmia



Perioperative Arrythmia

- Case
  - You get this patient through surgery
  - POD2, 2am, called for a HR of 140.

Perioperative Arrythmia

- randomized clinical trials examining the use of these agents in the perioperative period are scarce.

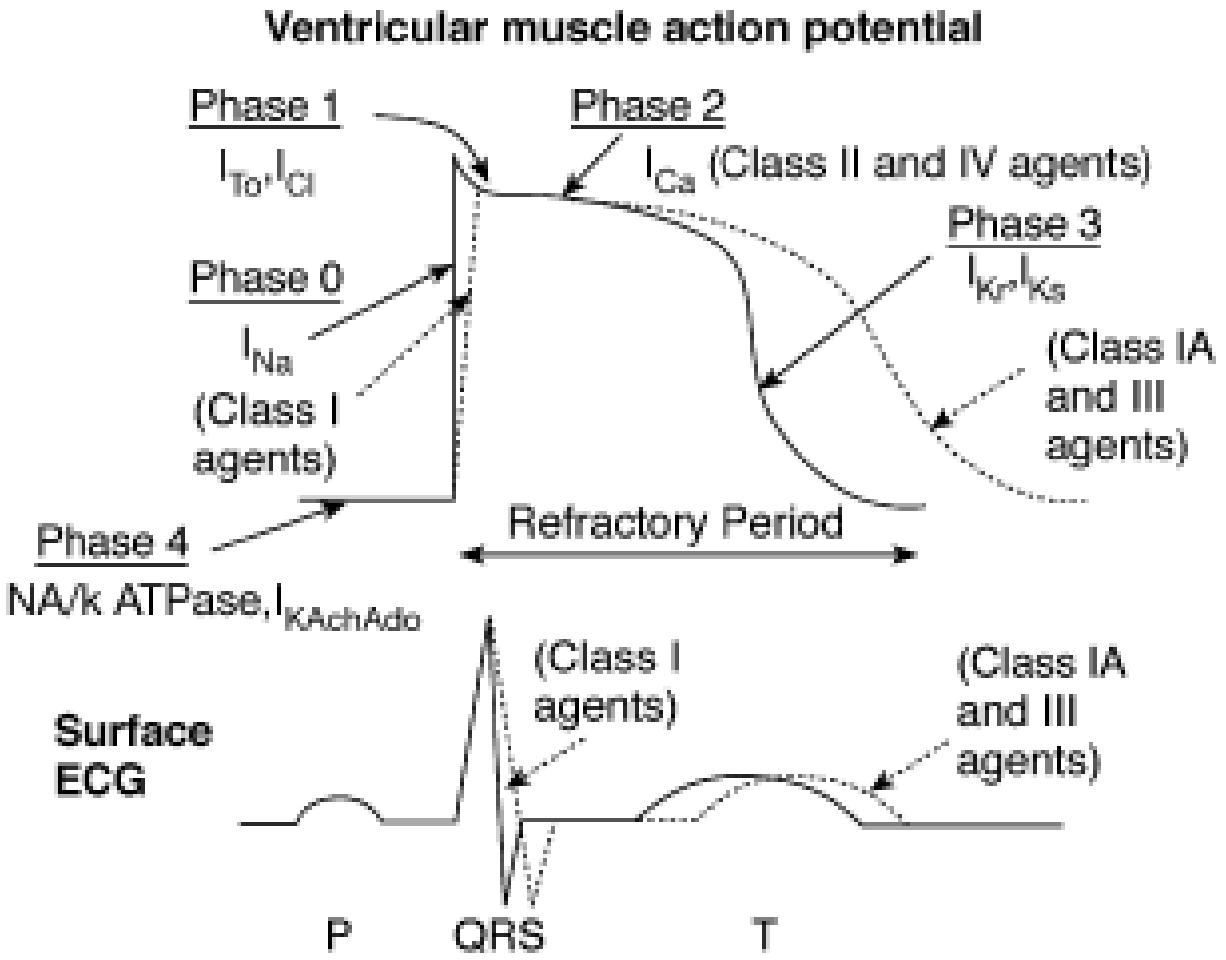
Perioperative Arrythmia

- Anti-arrhythmics and Ion Channels

- .All drugs modulating heart rhythm work through either
  - Adrenergic receptors
  - Second-messenger systems
  - Na, Ca, K channels

- Drug effect on the EKG can be predicted from the effect of cardiac action potential

Perioperative Arrythmia



Perioperative Arrythmia

- **Phase 0**
  - Initiation of action potential
  - Atrial and Ventricular myocytes: Na+ current
    - Na+ blockade: prolongs QRS
  - SA and AV node: Ca++ currents
    - Ca++ blockade: slows atrial rate, slows AV conduction
    - Slow ventricular response to atrial tachycardia
- **Phase 2 & 3**
  - Refractory period maintained by Ca++ influx, terminated by K+ efflux
    - Ca++ blockade: shortens refractory period, shortens QT, negative inotrope
    - K+ blockade: prolongs action potential and QT interval

Perioperative Arrythmia

Receptor	Class[2]	Drugs
Na^+, K^+ channels	IA	Procainamide, quinidine, amiodarone
Na^+ channels	IB	Lidocaine, phenytoin, *mexiletine, *tocainide
Beta adrenoceptors	II	Esmolol, amiodarone, propranolol, atenolol, *sotalol
K^+ channels	III	Bretylium, ibutilide, *sotalol, *dofetilide
Ca^{2+} channels	IV	Verapamil, diltiazem, amiodarone

Perioperative Arrythmia

Receptor	Class[2]	Drugs
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K^+ channels	III	Bretylium, ibutilide, *sotalol, *dofetilide
Ca^{2+} channels	IV	Verapamil, diltiazem, amiodarone

Perioperative Arrythmia

- **Phase 4**
  - Nodal cells spontaneously depolarize
  - Adenosine A1 receptors trigger K+ efflux, hyperpolarize the cell and oppose pacing.
  - Adenosine bolus
    - Slows SA rate
    - Blocks AV conduction (transient 3rd degree AV block)

Perioperative Arrythmia

- Supraventricular Tachycardia
  - Search for the **etiology!**
  - May precede a life-threatening condition being identified
  - Majority remain hemodynamically stable

Perioperative Arrythmia

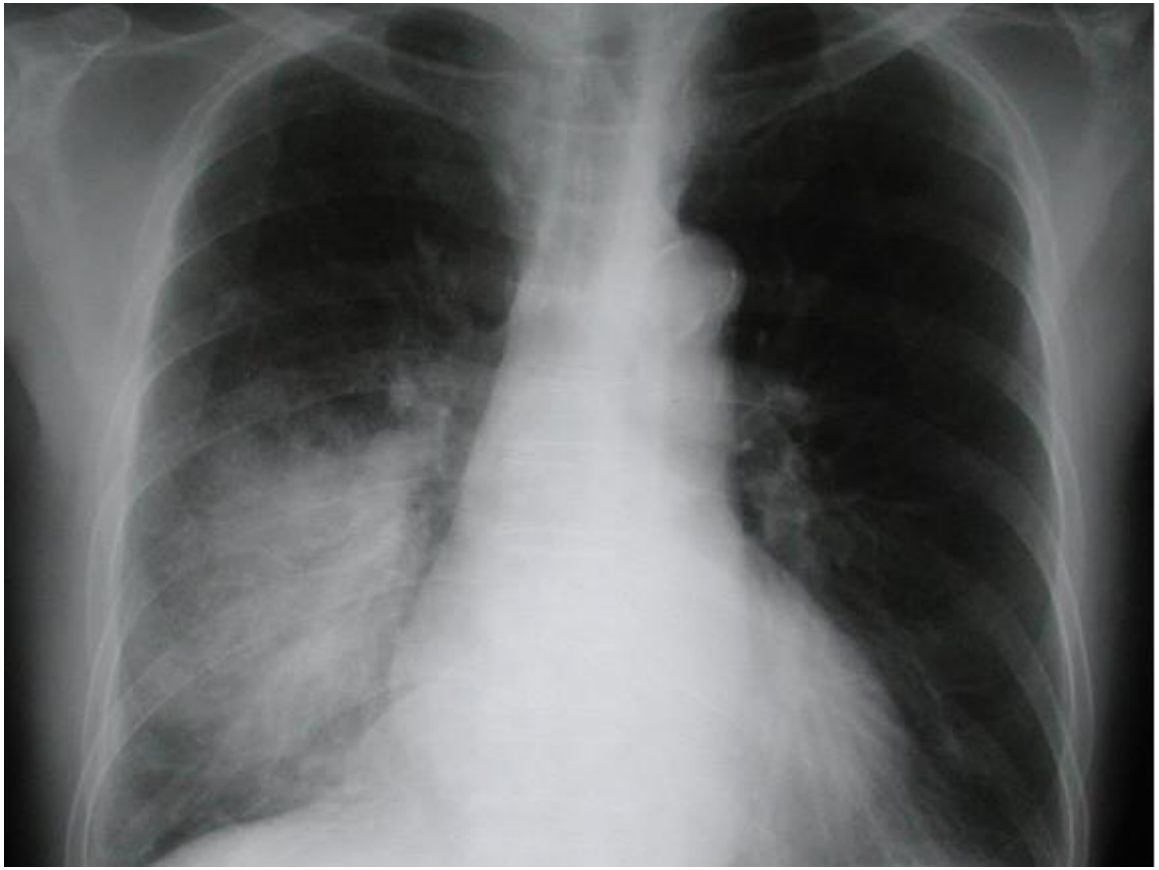
- SVT Reversible Causes
  - Hypoxemia
  - Hypercarbia
  - Acidosis
  - Hypotensions
  - Lytes
  - Mechanical (Chest tube, Swan-Ganz)
  - Hypothermia
  - Cardiac Ischemia
  - Adrenergic stimulation (pain, peritonitis)

  - **Post-operative leak**

Perioperative Arrythmia

- Approach to SVT
  - Immediate DC Cardioversion if hemodynamically unstable
  - Assess for etiology
  - Ventricular rate control
    - **Beta blockers**
      - Caution with LV dysfunction
    - **CCB**
      - **Diltiazem*** - caution in LV dysfunction
    - **Amiodarone**
- Unresolved predisposing factor increases likelihood of failed DC cardioversion
- 24 hour spontaneous sinus rate conversion ~60%

Sepsis



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Some History…

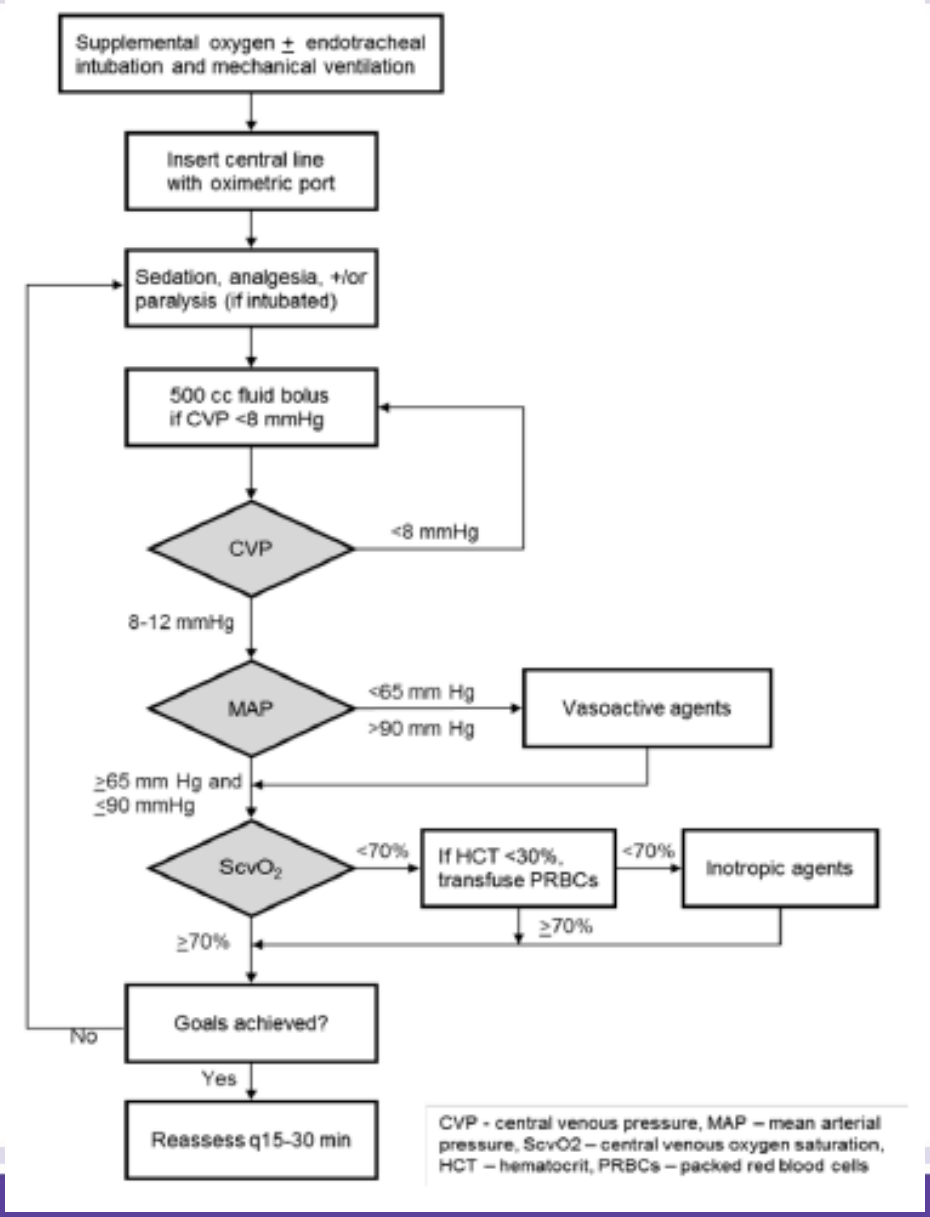
- 2001 – Emanuel Rivers

The New England Journal of Medicine

EARLY GOAL-DIRECTED THERAPY IN THE TREATMENT OF SEVERE SEPSIS AND SEPTIC SHOCK

EMANUEL RIVERS, M.D., M.P.H., BRYANT NGUYEN, M.D., SUZANNE HAVSTAD, M.A., JULIE RESSLER, B.S., ALEXANDRIA MUZZIN, B.S., BERNHARD KNOBLICH, M.D., EDWARD PETERSON, PH.D., AND MICHAEL TOMLANOVICH, M.D., FOR THE EARLY GOAL-DIRECTED THERAPY COLLABORATIVE GROUP*

EGDT


Supplemental oxygen ± endotracheal intubation and mechanical ventilation
Insert central line with oximetric port
Sedation, analgesia, +/or paralysis (if intubated)
500 cc fluid bolus if CVP <8 mmHg
CVP
<8 mmHg
8-12 mmHg
MAP
<65 mm Hg
>90 mm Hg
Vasoactive agents
≥65 mm Hg and ≤90 mmHg
ScvO2
<70%
If HCT <30%, transfuse PRBCs
<70%
Inotropic agents
≥70%
≥70%
Goals achieved?
No
Yes
Reassess q15-30 min
CVP - central venous pressure, MAP – mean arterial pressure, ScvO2 – central venous oxygen saturation, HCT – hematocrit, PRBCs – packed red blood cells

Schulich MEDICINE & DENTISTRY

TABLE 3. KAPLAN–MEIER ESTIMATES OF MORTALITY AND CAUSES OF IN-HOSPITAL DEATH.*

VARIABLE	STANDARD THERAPY (N=133)	EARLY GOAL-DIRECTED THERAPY (N=130)	RELATIVE RISK (95% CI)	P VALUE
	no. (%)			
In-hospital mortality†				
All patients	59 (46.5)	38 (30.5)	0.58 (0.38–0.87)	0.009
Patients with severe sepsis	19 (30.0)	9 (14.9)	0.46 (0.21–1.03)	0.06
Patients with septic shock	40 (56.8)	29 (42.3)	0.60 (0.36–0.98)	0.04
Patients with sepsis syndrome	44 (45.4)	35 (35.1)	0.66 (0.42–1.04)	0.07
28-Day mortality†	61 (49.2)	40 (33.3)	0.58 (0.39–0.87)	0.01
60-Day mortality†	70 (56.9)	50 (44.3)	0.67 (0.46–0.96)	0.03
Causes of in-hospital death‡				
Sudden cardiovascular collapse	25/119 (21.0)	12/117 (10.3)	—	0.02
Multiorgan failure	26/119 (21.8)	19/117 (16.2)	—	0.27

*CI denotes confidence interval. Dashes indicate that the relative risk is not applicable.

†Percentages were calculated by the Kaplan–Meier product-limit method.

‡The denominators indicate the numbers of patients in each group who completed the initial six-hour study period.

EGDT

Schulich MEDICINE & DENTISTRY

TABLE 4. TREATMENTS ADMINISTERED.*

TREATMENT	HOURS AFTER THE START OF THERAPY		
	0–6	7–72	0–72
Total fluids (ml)			
Standard therapy	3499±2438	10,602±6,216	13,358±7,729
EGDT	4981±2984	8,625±5,162	13,443±6,390
P value	<0.001	0.01	0.73
Red-cell transfusion (%)			
Standard therapy	18.5	32.8	44.5
EGDT	64.1	11.1	68.4
P value	<0.001	<0.001	<0.001
Any vasopressor (%)†			
Standard therapy	30.3	42.9	51.3
EGDT	27.4	29.1	36.8
P value	0.62	0.03	0.02
Inotropic agent (dobutamine) (%)			
Standard therapy	0.8	8.4	9.2
EGDT	13.7	14.5	15.4
P value	<0.001	0.14	0.15
Mechanical ventilation (%)			
Standard therapy	53.8	16.8	70.6
EGDT	53.0	2.6	55.6
P value	0.90	<0.001	0.02
Pulmonary-artery catheterization (%)‡			
Standard therapy	3.4	28.6	31.9
EGDT	0	18.0	18.0
P value	0.12	0.04	0.01

*Plus–minus values are means ±SD. Because some patients received a specific treatment both during the period from 0 to 6 hours and during the period from 7 to 72 hours, the cumulative totals for those two periods do not necessarily equal the values for the period from 0 to 72 hours. EGDT denotes early goal-directed therapy.

†Administered vasopressors included norepinephrine, epinephrine, dopamine, and phenylephrine hydrochloride.

‡All pulmonary-artery catheters were inserted while patients were in the intensive care unit.

ProCESS Trial

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MAY 1, 2014 VOL. 370 NO. 18

A Randomized Trial of Protocol-Based Care for Early Septic Shock

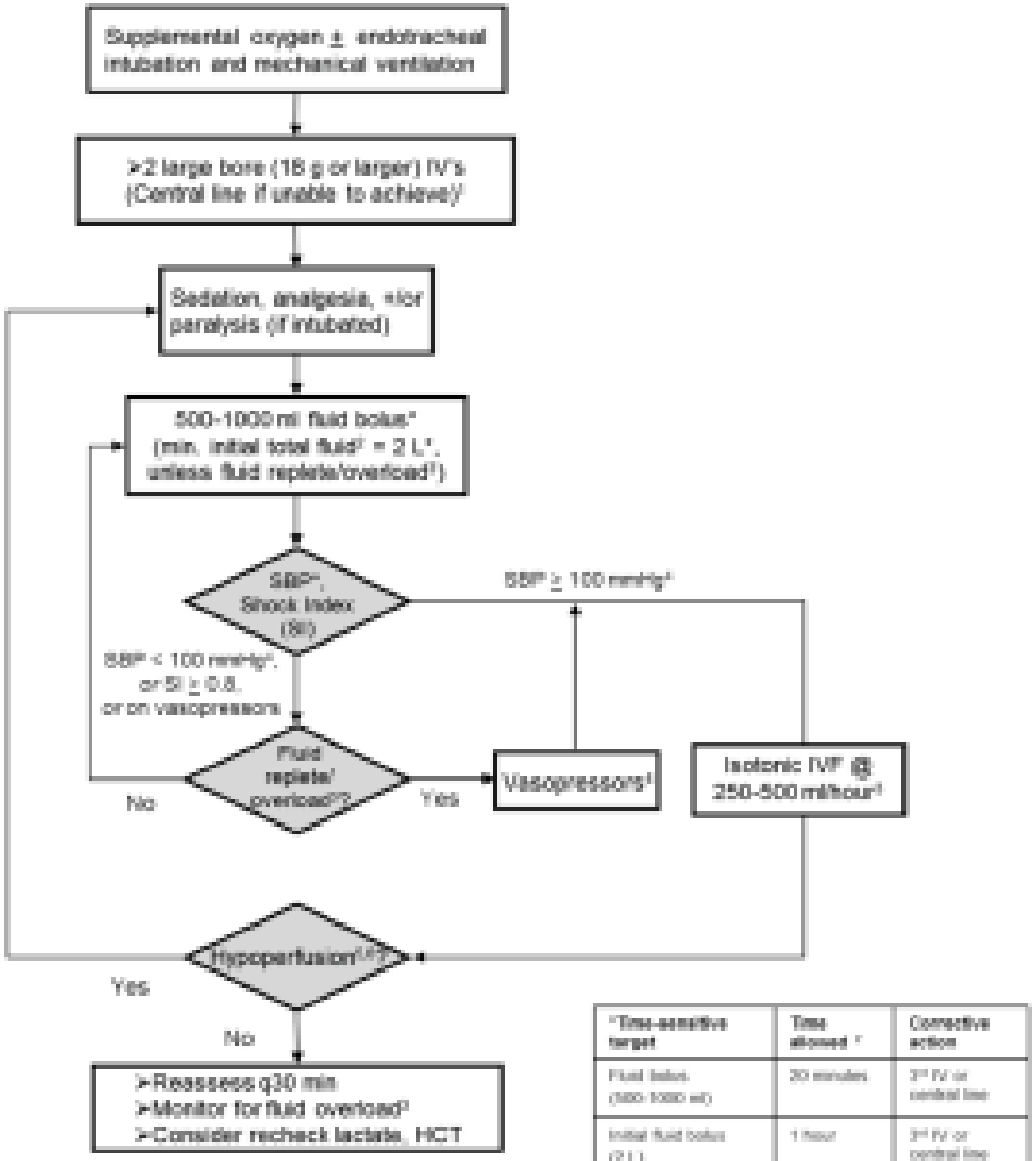
The ProCESS Investigators*

ProCESS Trial

- 31 academic EDs in **US**
  - Septic shock
    - By SIRS criteria

      and
    - Lactate >4, or Refractory hypotension
      - (sBP< 90 or vasopressors) after 20cc/kg fluid challenge over 30min (changed mid-study to >1L over 30 minutes)
- 1341 patients
- Comparisons
  - EGDT Protocol-based care (modified from Rivers, 2001)
  - Protocol-based Standard Care
  - Usual care (provider directed)
- Outcome: 60 day mortality

Figure S2. – Protocol for Standard Therapy.



"Time-sensitive" target	Time allowed [7]	Corrective action
Fluid bolus (500-1000 ml)	30 minutes	3rd IV or central line
Initial fluid bolus (2 L)	1 hour	3rd IV or central line
SBP ≥ 100 mmHg	1 hour	Vasopressors

ProCESS Trial

- Protocol-based Standard Therapy
  - Central line only for access. ScvO2 and CVP discouraged during first 6 hours
  - Only isotonic fluids
  - Fluid replete is based on clinical exam (venous distension, rales, decreased oxygenation, etc). All fluids held if identified.
  - Hypoperfusion based on BP, MAP, Lactate, Oliguria, Altered LOC, etc

ProCESS Trial

Schulich MEDICINE & DENTISTRY

Table 2. Outcomes.*

Outcome	Protocol-based EGDT (N=439)	Protocol-based Standard Therapy (N=446)	Usual Care (N=456)	P Value†
Death — no./total no. (%)				
In-hospital death by 60 days: primary outcome	92/439 (21.0)	81/446 (18.2)	86/456 (18.9)	0.83‡
Death by 90 days	129/405 (31.9)	128/415 (30.8)	139/412 (33.7)	0.66
New organ failure in the first week — no./total no. (%)				
Cardiovascular	269/439 (61.3)	284/446 (63.7)	256/456 (56.1)	0.06
Respiratory	165/434 (38.0)	161/441 (36.5)	146/451 (32.4)	0.19
Renal	12/382 (3.1)	24/399 (6.0)	11/397 (2.8)	0.04
Duration of organ support — days§				
Cardiovascular	2.6±1.6	2.4±1.5	2.5±1.6	0.52
Respiratory	6.4±8.4	7.7±10.4	6.9±8.2	0.41
Renal	7.1±10.8	8.5±12	8.8±13.7	0.92
Use of hospital resources				
Admission to intensive care unit — no. (%)	401 (91.3)	381 (85.4)	393 (86.2)	0.01
Stay in intensive care unit among admitted patients — days	5.1±6.3	5.1±7.1	4.7±5.8	0.63
Stay in hospital — days	11.1±10	12.3±12.1	11.3±10.9	0.25

ProCESS Trial

Schulich MEDICINE & DENTISTRY

Intervention	Protocol-based EGDT (N=439)	Protocol-based Standard Therapy (N=446)	Usual care (N=456)	p-value[g]
Pre-randomization				
Intravenous fluids[b] – mL	2254 ± 1472	2226 ± 1363	2083 ± 1405	0.15
Fluids per body weight (mL/kg)	30.5 ± 22.3	29.2 ± 19.1	28 ± 21	
Vasopressor use[c]	84 (19.1)	75 (16.8)	69 (15.1)	0.28
Dobutamine use	0 (0)	0 (0)	0 (0)	
Blood transfusion	5 (1.1)	7 (1.6)	9 (2.0)	0.63
Mechanical ventilation	60 (13.7)	65 (14.6)	63 (13.8)	0.93
Intravenous antibiotics	332 (75.6)	343 (76.9)	347 (76.1)	0.91
Corticosteroids	41 (9.3)	42 (9.4)	38 (8.3)	0.82
Activated protein C	0 (0)	0 (0)	0 (0)	
Randomization to hour 6[d]				
Resuscitation elements				
Central venous catheterization	411 (93.6)	252 (56.5)	264 (57.9)	<0.0001
Central venous oximeter catheterization[e]	409 (93.2)	18 (4.0)	16 (3.5)	<0.0001
Intravenous fluids – mL	2805 ± 1957	3285 ± 1743	2279 ± 1881	<0.0001
Vasopressor use	241 (54.9)	233 (52.2)	201 (44.1)	0.003
Dobutamine use	35 (8)	5 (1.1)	4 (0.9)	<0.0001
Blood transfusion	63 (14.4)	37 (8.3)	34 (7.5)	0.001
Ancillary care				
Mechanical ventilation	116 (26.4)	110 (24.7)	99 (21.7)	0.25
Tidal volume, mL/kg predicted body weight[f]	8.5 ± 2.4	8.1 ± 1.6	8.0 ± 1.8	0.11
Tidal volume, mL/kg body weight	6.7 ± 2.1	6.5 ± 1.9	6.8 ± 2.1	0.32
Intravenous antibiotics	428 (97.5)	433 (97.1)	442 (96.9)	0.90
Corticosteroids	54 (12.3)	48 (10.8)	37 (8.1)	0.16
Activated protein C	1 (0.2)	1 (0.2)	0 (0)	0.55

ProCESS Trial

Schulich MEDICINE & DENTISTRY

Intervention	Protocol-based EGDT (N=439)	Protocol-based Standard Therapy (N=446)	Usual care (N=456)	p-value[8]
Processes of care from 6-72 h				
Intravenous fluids – mL	4458 ± 3878	4918 ± 4308	4354 ± 3882	0.08
Vasopressor use	209 (47.6)	208 (46.6)	197 (43.2)	0.38
Dobutamine use	19 (4.3)	9 (2.0)	10 (2.2)	0.08
Blood transfusion	87 (19.8)	93 (20.9)	82 (18.0)	0.54
Mechanical ventilation	148 (33.7)	140 (31.4)	127 (27.9)	0.16
Tidal volume, mL/kg predicted body weight	8.5 ± 2.5	8.6 ± 2.6	8.1 ± 1.8	0.05
Tidal volume, mL/kg body weight	6.7 ± 2.3	6.6 ± 2.4	6.6 ± 2.2	0.81
Processes of care from 0-72 h				
Intravenous fluids – mL	7253 ± 4605	8193 ± 4989	6633 ± 4560	<0.0001
Vasopressor use	265 (60.4)	273 (61.2)	245 (53.7)	0.05
Dobutamine use	41 (9.3)	11 (2.5)	13 (2.9)	<0.0001
Blood transfusion	120 (27.3)	107 (24.0)	102 (22.4)	0.22
Mechanical ventilation	159 (36.2)	152 (34.1)	135 (29.6)	0.10
Tidal volume, mL/kg predicted body weight	8.5 ± 2.5	8.4 ± 2.4	8.1 ± 1.8	0.03
Tidal volume, mL/kg body weight	6.7 ± 2.2	6.6 ± 2.2	6.7 ± 2.2	0.55

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Goal-Directed Resuscitation for Patients with Early Septic Shock

The ARISE Investigators and the ANZICS Clinical Trials Group*

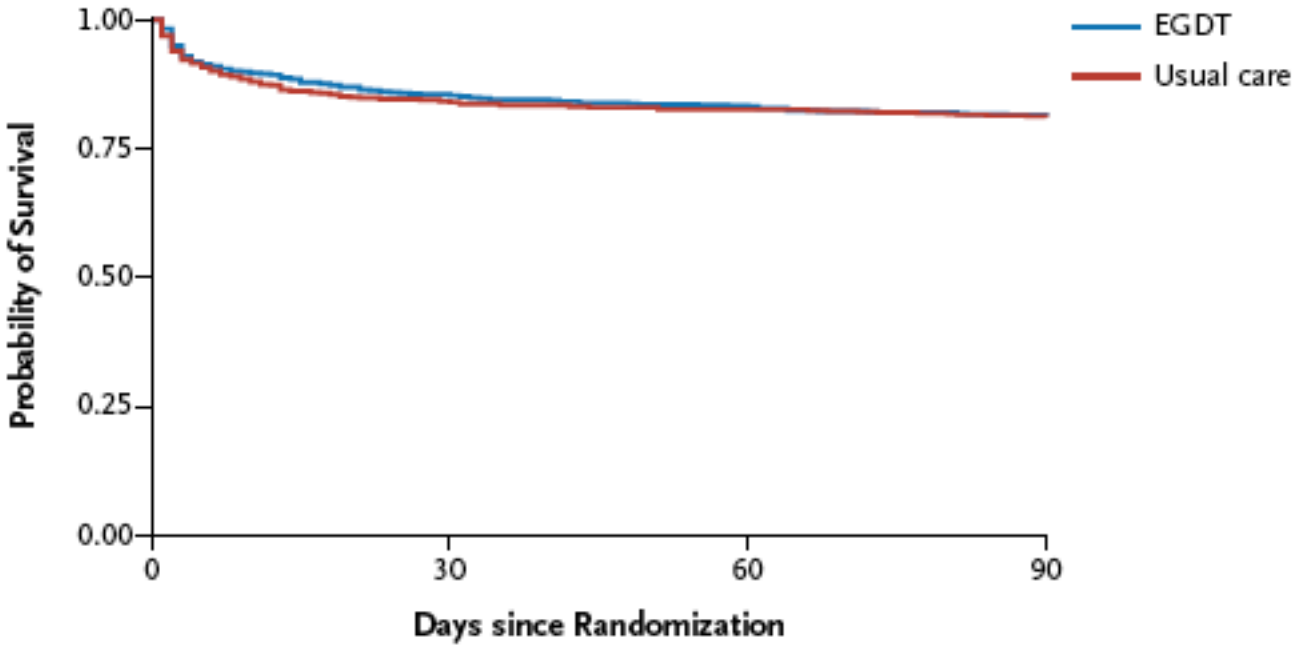
ABSTRACT

ARISE Trial

- 51 tertiary / non-tertiary, urban/rural ER
- Australia / Finland / Hing King / Ireland / New Zealand
- Septic shock
  - By SIRS criteria

    and
  - Lactate >4, or Refractory hypotension
    - sBP<90 or MAP < 65 after 1L over 60min, or lactate > 4
- 1600 patients
- Comparisons
  - EGDT Protocol-based care (as per Rivers, 2001)
  - Usual care (provider directed)
    - **No protocol prompts**
    - **ScvO2 not permitted**
- Outcome: 90 day mortality

ARISE Trial



No. at Risk				
EGDT	792	677	660	646
Usual care	796	670	657	646

ARISE Trial

Intervention	0 to 6 hours			6 to 72 hours[b]		
	EGDT (N = 793)	Usual care (N = 798)	P Value	EGDT (N = 782)	Usual care (N = 778)	P Value
Mechanical ventilation - no./total no.						
Invasive	176/793 (22.2)	179/798 (22.4)	0.91	211/782 (27.0)	210/778 (27.0)	1.00
Non-invasive	100/793 (12.6)	84/798 (10.5)	0.19	91/782 (11.6)	106/778 (13.6)	0.24
Intravenous fluids,[c]						
Total - ml	1964 ±1415	1713 ± 1401	<0.001	4274 ± 3071	4382 ± 3136	0.51
Total - ml/kg	26.8 ± 20.6	23.2 ± 21.2	<0.001	58.9 ± 46.2	59.2 ± 45.1	0.87
Crystalloids - ml	1547 ± 1351	1374 ± 1335	0.01	3520 ± 2792	3608 ± 2783	0.54
Crystalloids - ml/kg	21.1 ± 19.8	18.7 ± 19.9	0.02	48.7 ± 42.3	48.8 ± 39.1	0.93
Colloids - ml	323 ± 672	249 ± 552	0.02	345 ± 777	328 ± 808	0.68
Colloids - ml/kg	4.4 ± 8.9	3.3 ± 7.5	0.01	4.8 ± 10.6	4.5 ± 11.2	0.63
Vasopressor infusion - no./total no. (%)[d]	528/793 (66.6)	461/798 (57.8)	<0.001	460/782 (58.8)	401/778 (51.5)	0.004

ARISE Trial

Intervention	0 to 6 hours			6 to 72 hours[b]		
	EGDT (N = 793)	Usual care (N = 798)	P Value	EGDT (N = 782)	Usual care (N = 778)	P Value
Blood products						
Red-cell transfusion - no./total no. (%)	108/793 (13.6)	56/798 (7.0)	<0.001	86/782 (11.0)	92/778 (11.8)	0.61
Red-cell transfusion volume - ml	56.1 ± 164	40.2 ± 167	0.06	57.6 ± 211.5	76.9 ± 280.0	0.12
Platelet transfusion - no./total no. (%)	34/793 (4.3)	28/798 (3.5)	0.42	47/782 (6.0)	48/778 (6.2)	0.90
Fresh frozen plasma - no./total no. (%)	41/793 (5.2)	35/798 (4.4)	0.46	43/782 (5.5)	50/778 (6.4)	0.44
Dobutamine infusion - no./total no. (%)	122/793 (15.4)	21/798 (2.6)	< 0.001	74/782 (9.5)	39/788 (5.0)	<0.001
Monitoring inserted - no./total no[e]						
Arterial catheter	725/793 (91.4)	609/798 (76.3)	< 0.001	9/782 (1.2)	32/778 (4.10)	<0.001
Central venous catheter	109/793 (13.7)	494/798 (61.9)	< 0.001	11/782 (1.4)	36/778 (4.6)	< 0.001
$ScvO_2$ central venous catheter[f]	714/793 (90.0)	3/798 (0.4)	< 0.001	0/782 (0)	0/778 (0)	1.00
Pulmonary artery catheter	1/793 (0.1)	9/798 (1.1)	0.01	3/782 (0.4)	7/778 (0.9)	0.20
PiCCO	20/793 (2.5)	22/798 (2.8)	0.77	24/782 (3.1)	27/778 (3.5)	0.66

ProMISe Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Trial of Early, Goal-Directed Resuscitation for Septic Shock

Paul R. Mouncey, M.Sc., Tiffany M. Osborn, M.D., G. Sarah Power, M.Sc., David A. Harrison, Ph.D., M. Zia Sadique, Ph.D., Richard D. Grieve, Ph.D., Rahi Jahan, B.A., Sheila E. Harvey, Ph.D., Derek Bell, M.D., Julian F. Bion, M.D., Timothy J. Coats, M.D., Mervyn Singer, M.D., J. Duncan Young, D.M., and Kathryn M. Rowan, Ph.D., for the ProMISe Trial Investigators*

ProMISe Trial

- 56 hospitals in England
  - *Hospitals did not routinely use EGDT that included ScvO2*
- Sepsis
  - At least 2/4 SIRS
  - Hypotension (sBP<90 or MAP<65) despite 1L crystalloid *or* lactate > 4
- 1260 patients
- Comparisons
  - 6 hr EGDT Resuscittion protocol
  - Provider directed “usual care”
- Outcome: all cause 90 day mortality

ProMISe Trial

Table 3. Study Outcomes.*

Outcome	EGDT (N=625)	Usual Care (N=626)	Incremental Effect (95% CI)	P Value
Clinical effectiveness				
Primary outcome: death from any cause at 90 days — no./total no. (%)	184/623 (29.5)	181/620 (29.2)		
Relative risk			1.01 (0.85 to 1.20)	0.90†
Absolute risk reduction — percentage points			−0.3 (−5.4 to 4.7)	
Unadjusted odds ratio			1.02 (0.80 to 1.30)	
Adjusted odds ratio			0.95 (0.74 to 1.24)	0.73

ProMISe Trial

Schulich MEDICINE & DENTISTRY

Table 2. Interventions Delivered during and after the 6-Hour Intervention Period.*

Intervention	Hour 0 to 6		Hour >6 to 72	
	EGDT (N = 625)	Usual Care (N = 626)	EGDT (N = 608)	Usual Care (N = 607)
Supplemental oxygen — no./total no. (%)	558/623 (89.6)	557/625 (89.1)	520/603 (86.2)	515/603 (85.4)
Insertion of central venous catheter with $Scvo_2$ monitoring capability				
Patients — no./total no. (%)	545/624 (87.3)	2/625 (0.3)	NA	NA
Before hour 1 — no./total no. (%)	459/543 (84.5)	NA	NA	NA
Insertion of any central venous catheter				
Patients — no./total no. (%)	575/624 (92.1)	318/625 (50.9)	NA	NA
Median time from randomization to insertion (IQR) — hr	1.1 (0.8–1.5)	1.4 (0.6–2.9)	NA	NA
Insertion of arterial catheter				
Patients — no./total no. (%)	462/623 (74.2)	389/625 (62.2)	NA	NA
Median time from randomization to insertion (IQR) — hr	1.1 (0.4–1.9)	1.0 (0.2–1.9)	NA	NA
Median total intravenous fluids (IQR) — ml†	2000 (1150–3000)	1784 (1075–2775)	3623 (1800–6060)	3981 (1895–6291)
Intravenous colloids				
Patients — no./total no. (%)†	197/623 (31.6)	180/625 (28.8)	171/603 (28.4)	150/603 (24.9)
Median volume (IQR) — ml	1000 (500–1500)	750 (500–1000)	750 (500–1750)	750 (500–1500)
Intravenous crystalloids				
Patients — no./total no. (%)†	584/623 (93.7)	597/625 (95.5)	537/603 (89.1)	543/603 (90.0)
Median volume (IQR) — ml	1750 (999–2750)	1500 (900–2380)	3403 (1576–5647)	3694 (1832–5911)
Vasopressor — no./total no. (%)	332/623 (53.3)	291/625 (46.6)	349/603 (57.9)	317/603 (52.6)
Dobutamine — no./total no. (%)	113/623 (18.1)	24/625 (3.8)	107/603 (17.7)	39/603 (6.5)
Red-cell transfusion				
Patients — no./total no. (%)	55/623 (8.8)	24/625 (3.8)	76/603 (12.6)	51/603 (8.5)
Median volume (IQR) — ml	309 (285–577)	535 (305–607)	351 (291–579)	552 (317–620)
Platelets				
Patients — no./total no. (%)	11/623 (1.8)	10/625 (1.6)	23/603 (3.8)	25/603 (4.1)
Median volume (IQR) — ml	315 (200–340)	180 (163–342)	274 (182–366)	187 (172–357)
Fresh-frozen plasma				
Patients — no./total no. (%)	15/623 (2.4)	14/625 (2.2)	28/603 (4.6)	30/603 (5.0)
Median volume (IQR) — ml	1007 (539–1095)	793 (526–1085)	587 (483–1000)	846 (528–1057)
ICU admission — no./total no. (%)	551/625 (88.2)	467/626 (74.6)	NA	NA
Median time from randomization to ICU admission (IQR) — hr	1.2 (0.4–2.8)	1.2 (0.3–2.8)	NA	NA

Take away thoughts…

- Source Control and Early Antibiotics – The Cornerstone of Sepsis management!!!

- Not all septic patients need a central line
- Don’t put too much emphasis on CVP
- Don’t start Dobutamine based on ScvO2 alone
- Keep the blood for the anemic patients

Antibiotic Prophylaxis

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Antibiotic Prophylaxis

Clinical practice guidelines for antimicrobial prophylaxis in surgery

DALE W. BRATZLER, E. PATCHEN DELLINGER, KEITH M. OLSEN, TRISH M. PERL, PAUL G. AUWAERTER, MAUREEN K. BOLON, DOUGLAS N. FISH, LENA M. NAPOLITANO, ROBERT G. SAWYER, DOUGLAS SLAIN, JAMES P. STEINBERG, AND ROBERT A. WEINSTEIN

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Antibiotic Prophylaxis

- Optimal time for administration of preoperative doses is within 60 minutes before surgical incision
- Vancomycin infusion should start 120 minutes before incision
- For MRSA colonized patient, reasonable to **add** Vancomycin to recommended agent
- **Patients receiving therapeutic antimicrobials for an infection before surgery should be given additional prophylaxis before surgery**

Antibiotic Prophylaxis

Antiobiotic	Adult Dose	Redosing Interval
Cefazolin	2g (3g if >120kg)	4 hours
Ceftriaxone	2g	n/a
Clindamycin	900mg	6 hours
Gentamycin	5mg/kg	n/a
Tobramycin	1.5mg/kg	n/a
Pip-Tazo	3.375g	2 hours
Vancomycin	15mg/kg	n/a

Beta-lactam Allergy

- Cross reaction between penicillins, cephalosporins, and carbapenems are uncommon, but avoid in Type I (IgE mediated)
  - Anaphylaxis,
  - Urticaria
  - Bronchospasm
  - (Stevens-Johnson Syndrome)

- Cephalosporins and carbapenems can safely be used in patients with an allergic reaction to penicillins that is not an IgE mediated reaction

Antibiotic Prophylaxis – Gastroduodenal

Procedure	Recommended Antibiotic	Alternative for beta-lactam allergy
Gastroduodenal *(with entry into lumen)*	Cefazolin	Vancomycin + Gent/Tobra Clindamycin + Gent/Tobra
Gastroduodenal *(without entry into lumen, **low risk**)*	**NONE**	**NONE**
Gastroduodenal *(without or entry into lumen, **high risk**)*	Cefazolin	Vancomycin + Gent/Tobra Clindamycin + Gent/Tobra

Antibiotic Prophylaxis – Biliary

Procedure	Recommended Antibiotic	Alternative for beta-lactam allergy
Laparoscopic Biliary Tract (elective, low risk)	**NONE***	**NONE***
Laparoscopic Biliary Tract (elective, **high risk**)	Cefazolin Ceftriaxone (*infectious indication, e.g. acute chole*)	Vanco + Gent/Tobra Clindamycin + Gent/Tobra Flagyl + Gent/Tobra
Open Biliary Tract	Cefazolin, Ceftriaxone (infectious indication)	Vanco + Gent/Tobra Clindamycin + Gent/Tobra Flagyl + Gent/Tobra

Laparoscopic Cholecystectomy

- Risk factors include
  - emergency procedures
  - diabetes
  - anticipated procedure duration exceeding 120 minutes
  - risk of intraoperative gallbladder rupture
  - age of >70
  - open cholecystectomy, risk of conversion to open
  - ASA classification of ≥3,
  - episode of biliary colic within 30 days before the procedure,
  - Repeat intervention in less than a month for noninfectious complications of prior biliary operation, acute cholecystitis,
  - Jaundice
  - pregnancy,
  - immunosuppression.

Laparoscopic Cholecystectomy

- Some of these risk factors cannot be determined before the surgical intervention,
- Reasonable to give a single dose of antimicrobial prophylaxis to all patients undergoing laparoscopic cholecystectomy.

Antibiotic Prophylaxis – Breast

Procedure	Recommended Antibiotic	Alternative for beta-lactam allergy
Breast *(clean)*	None	None
Breast *(cancer, clean-contaminated)*	Cefazolin	Vancomycin Clindamycin

Antibiotic Prophylaxis

Procedure	Recommended Antibiotic	Alternative for beta-lactam allergy
Uncomplicated Appendicitis	Cefazolin + Flagyl	Clindamycin + Gent/Tobra Flagyl + Gent/Tobra
Hernia Repair *(mesh or non-mesh)*	Cefazolin	Clindmycin Vancomycin
Colorectal	Cefazolin + Flagyl	Clindamycin + Gent/Tobra Flagyl + Gent/Tobra
Small Bowel, *non-obstrcuted*	Cefazolin	Clindamycin + Gent/Tobra
Small Bowel, *obstrcuted*	Cefazolin + Flagyl	Flagyl + Gent/Tobra

Antibiotic Prophylaxis – BPIGS

Indication	Regimen (no β-lactam allergy)	Regimen (β -lactam allergy)
Gastroduodenal/Esophageal (includes bariatric surgery)	cefazolin*	vancomycin & gentamicin
	Dose: 2 g IV	Dose: vancomycin: 1 g IV gentamicin: 1.5-2 mg/kg IV
Biliary/Pancreas/Liver**	cefazolin*	vancomycin & gentamicin
	Dose: 2 g IV	Dose: vancomycin: 1 g IV gentamicin: 1.5-2 mg/kg IV
Low Risk Laparoscopic Cholecystectomy (i.e. no jaundice, age<70 yrs, non-diabetic, no acute inflammation)	No prophylaxis	
Breast/Hernia/Thyroid/ Parathyroid	cefazolin*	vancomycin
	Dose: 2 g IV	Dose: vancomycin: 1 g IV
Colon, Rectum, Small Bowel and Non-Perforated Appendicitis**	cefazolin* & metronidazole	metronidazole & gentamicin
	Dose: metronidazole: 500 mg IV cefazolin*: 2 g IV gentamicin: 1.5-2 mg/kg IV	Dose: metronidazole: 500 mg IV gentamicin: 1.5-2 mg/kg IV
Low Risk Anorectal Procedures (i.e. hemorrhoidectomy, fistulotomy and sphincterotomy for fissure)	No prophlaxis	
* For patients with known colonization with MRSA, vancomycin should be substituted for cefazolin		
** Patients who have been on antibiotics preoperatively (e.g Crohn's patients) or have had instrumentation of their biliary tree should also receive gentamycin		

Antibiotic Prophylaxis – BPIGS

Intraoperative Antimicrobial Re-Administration Guidelines for Operations Lasting > 3 hours

Antimicrobial	Recommended Dosing Interval
cefazolin 1 g IV	q3h
gentamicin dosed at 2mg/kg	q6h
metronidazole	q8h
vancomycin	q12h
clindamycin	q8h