Literature Updates
Trauma and Emergency General Surgery

Mayo School of Continuous Professional Development

2nd Annual Inpatient Medicine for NPs & Pas:
Hospital Care from Admission to Discharge

Wednesday-Saturday, October 19-22, 2016
Sawgrass Marriott Hotel • Ponte Vedra Beach, Florida
Financial disclosure

• No financial disclosures
Acute care surgery

- An evolving specialty with three components:
  - Trauma
  - Critical care
  - Emergency general surgery
Objectives

• Review literature updates (big topics) from trauma and emergency general surgery

• Can’t cover everything

• Papers that *should* change your practice…if they haven’t already
Trauma literature updates


The PROPPR trial—Pragmatic, Randomized Optimal Platelet and Plasma Ratios

• Injury remains leading cause of death for the US population age 1-44 years

• ~20% to 40% of trauma deaths occurring after hospital admission involve massive hemorrhage

• Damage control resuscitation is defined as rapid hemorrhage control through early administration of blood products in a balanced ratio (1:1:1 plasma to platelets to RBCs)
  • Closest to whole blood

• Minimize crystalloid fluids

The PROPPR trial—Background

• Damage control resuscitation was developed (2004) to treat intravascular volume deficits, the acute coagulopathy of trauma, preserve oxygen-carrying capacity, repair the endothelium, and prevent dilutional coagulopathy
  • Standard of care
  • Improved outcomes

• Retrospective studies to date have reported beneficial outcomes across a wider range of blood product ratios or goal-directed approaches

The PROPPR trial

• Compared the effectiveness and safety of a 1:1:1 transfusion ratio of plasma, platelets, and RBCs to a 1:1:2 ratio

• Multisite, RCT
  • 12 Level 1 centers in North America
  • 680 severely injured pts admitted directly from scene and were predicted to require massive transfusion between 8/2012 and 12/2013
  • ABC score
  • Received 1 U of RBC in first hour

The PROPPR trial—Design

- 338 pts received 1:1:1; 342 received 1:1:2 and local standard of care interventions (uncontrolled)
- Primary outcomes: 24-hour and 30-day all-cause mortality
- Ancillary outcomes: time to hemostasis, blood product volumes transfused, complications, incidence of surgical procedures, and functional status

The PROPPPR trial—Results

- No significant differences were detected in mortality at 24 hours or at 30 days
- Exsanguination was significantly decreased in the 1:1:1 group as was death associated with exsanguination
- More patients in the 1:1:1 group achieved hemostasis than in the 1:1:2 group

<table>
<thead>
<tr>
<th></th>
<th>1:1:1 Group (n = 338)</th>
<th>1:1:2 Group (n = 342)</th>
<th>Difference (95% CI), %</th>
<th>Adjusted RR (95% CI)</th>
<th>P Value^3</th>
</tr>
</thead>
<tbody>
<tr>
<td>24-h Mortality, No. (%)^b</td>
<td>43 (12.7)</td>
<td>58 (17.0)</td>
<td>-4.2 (-9.6 to 1.1)</td>
<td>0.75 (0.52 to 1.08)</td>
<td>.12</td>
</tr>
<tr>
<td>30-d Mortality, No. (%)^b</td>
<td>75 (22.4)</td>
<td>89 (26.1)</td>
<td>-3.7 (-10.2 to 2.7)</td>
<td>0.86 (0.65 to 1.12)</td>
<td>.26</td>
</tr>
<tr>
<td>Achieved hemostasis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.006</td>
</tr>
<tr>
<td>No. (%)</td>
<td>291 (86.1)</td>
<td>267 (78.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The PROPPR trial—Results

- Despite the 1:1:1 group receiving more plasma and platelets and similar amounts of red blood cells over the first 24 hours, no differences between the 2 groups were found for ARDS, MOF, venous thromboembolism, sepsis, and transfusion-related complications

The PROPPR trial—Conclusions

- 1:1:1 transfusion ratio for severely injured trauma patients is safe and provides more rapid hemostasis and improved survival from exsanguination at 24 hours compared with a 1:1:2 ratio without significant increases in mortality.

- A 1:1:1 transfusion ratio leads to increased use of both plasma and platelets.

- Consider using a 1:1:1 transfusion protocol, starting with the initial units transfused while patients are actively bleeding; transition to laboratory-guided treatment once hemorrhage control is achieved.

The PROPPR trial--Limitations

• Underpowered to detect mortality difference as mortality was lower than expected in the 1:1:2 group

• Plasma or platelets?

• Not blinded after enrollment

• Patients with unsurvivable brain injury were not excluded
  • 23% of deaths at 24 hours and 38% of all deaths at 30 days

Four-factor PCC vs. Plasma—Background

• Rapid reversal of vitamin K antagonist (VKA)-induced anticoagulation is often necessary for patients needing urgent surgical or invasive procedures

• The optimum means of VKA reversal has not been established in comparative clinical trials

Four-factor PCC vs. Plasma—Objective

- Compare the efficacy and safety of four-factor prothrombin complex concentrate (4F-PCC) with that of plasma in VKA-treated patients needing urgent surgical or invasive procedures.
Four-factor PCC vs. Plasma—Design

- Multicenter, RCT, 33 centers
- Pts received Vit. K and a single dose of either 4F-PCC or plasma
  - Dosing based on INR and weight
- Primary endpoint: effective hemostasis
- Co-primary endpoint: rapid INR reduction (≤1.3 30 min after infusion end)
- Examined non-inferiority and subsequently superiority
- AEs reported to day 10; SAEs reported to day 45.

Four-factor PCC vs. Plasma—Results

• 181 patients were randomized (4F-PCC n=90 intention to treat (86 true population); plasma n=91 (76))
  • Had INR >2.0 and needed surgery within 24 hours

• Effective hemostasis was achieved in 78 (90%) patients in the 4F-PCC group compared with 61 (75%) patients in the plasma group
  • Both non-inferiority and superiority demonstrated

Four-factor PCC vs. Plasma—Results

Four-factor PCC vs. Plasma—Results

- Rapid INR reduction was achieved in 48 (55%) patients in the 4F-PCC group compared with eight (10%) patients in the plasma group.
  - Both non-inferiority and superiority demonstrated

- 49 (56%) patients receiving 4F-PCC had adverse events compared with 53 (60%) patients receiving plasma.

## Four-factor PCC vs. Plasma—AEs and SAEs

<table>
<thead>
<tr>
<th>Event</th>
<th>4F-PCC (n=88)</th>
<th>Plasma (n=88)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any adverse event</td>
<td>49 (56%)</td>
<td>53 (60%)</td>
</tr>
<tr>
<td>Related adverse event*</td>
<td>8 (9%)</td>
<td>15 (17%)</td>
</tr>
<tr>
<td>Adverse event leading to treatment discontinuation</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Serious adverse event</td>
<td>22 (25%)</td>
<td>23 (26%)</td>
</tr>
<tr>
<td>Related serious adverse event*</td>
<td>3 (3%)</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>Adverse events of interest</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deaths to day 45†</td>
<td>3 (3%)</td>
<td>8 (9%)</td>
</tr>
<tr>
<td>Thromboembolic adverse event‡</td>
<td>6 (7%)</td>
<td>7 (8%)</td>
</tr>
<tr>
<td>Fluid overload or similar cardiac event</td>
<td>3 (3%)</td>
<td>11 (13%)</td>
</tr>
<tr>
<td>Bleeding after primary outcome assessment</td>
<td>3 (3%)</td>
<td>4 (5%)</td>
</tr>
</tbody>
</table>

Adverse events with missing treatment associations were classified as related to treatment. *Defined as events that were related to study treatment according to the investigator. †One additional death in the 4F-PCC group occurred after study day 45 (day 48; worsening of cardiopulmonary disease). ‡Thromboembolic adverse events included: six patients (seven events) in the 4F-PCC group (deep-vein thrombosis [two events], thrombosis, ischaemic stroke [two events], vena cava filter insertion, and catheter-related complication) and seven patients (seven events) in the plasma group (acute myocardial infarction [two events], deep-vein thrombosis, ischaemic stroke [two events], pulmonary embolism, and transient ischaemic attack). §One deep-vein thrombosis and one stroke occurred in the same patient. 4F-PCC=four-factor prothrombin complex concentrate.
Four-factor PCC vs. Plasma—Conclusion

- 4F-PCC is non-inferior and superior to plasma for rapid INR reversal and effective hemostasis in patients needing VKA reversal for urgent surgical or invasive procedures.

Four-factor PCC vs. Plasma—Limitations

• Open label/not-blinded
• Timing of plasma infusion was variable
• Study not powered to detect differences in safety outcomes
• Hemostatic efficacy endpoint is subjective
• Additional considerations:
  • Cost
  • Availability

Hemorrhage Management—Pelvic trauma—Background

- Pts presenting with hemodynamic instability associated with pelvic fractures remain one of the biggest challenges for trauma care providers
  - Multiple sources: venous, arterial, fractured bone

- There is no consensus as to the optimal treatment paradigm for patients presenting with hemorrhage from severe pelvic fracture.

- **Objective:** Determine the methods of hemorrhage control currently being used in clinical practice

Hemorrhage Management—Pelvic trauma—Design

• Prospective, observational multi-center study (11 Level 1 centers)

• Enrolled pts with traumatic pelvic fracture

• Recorded: Demographic data, admission vital signs, presence of shock on admission (systolic blood pressure < 90 mm Hg or heart rate > 120 beats per minute or base deficit < -5), method of hemorrhage control, transfusion requirements, and clinical outcome

Hemorrhage Management—Pelvic trauma—Results

• Centers compiled 1,339 pts with pelvic fractures over a two year period ending in January 2015

• Just over half were male with a mean age of 47 +/- 20 years

• Typical mechanisms were MVC, falls, auto versus pedestrian and MCC

• Mean injury severity score (ISS) was severe at 19.

• Average ICU and overall length of stay was long at 8 and 11 days respectively.

• The diagnosis was made by pelvic x-ray and CT imaging.

Hemorrhage Management-Pelvic trauma—Results

• There were 178 (13.3%) who presented meeting the criteria for shock with a mean ISS of 28.

• Management included pelvic binders (18.5%), therapeutic angioembolization (16.9%), External fixation (9.6%), preperitoneal pelvic packing (5.1%), Resuscitative endovascular balloon aortic occlusion REBOA (2.8%), combination (17.8%).

• The in-hospital mortality overall was 9.0% but for those who presented in shock it rose to 32.0%.
Hemorrhage Management—Pelvic trauma—Results

**TABLE 5. Pelvic Fracture Diagnosis/Management for Patients Admitted in Shock (n = 178 Patients)**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Percent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic X-ray</td>
<td>161 (90.4%)</td>
</tr>
<tr>
<td>Pelvic binder</td>
<td>33 (18.5%)</td>
</tr>
<tr>
<td>CT scan</td>
<td>151 (84.8%)</td>
</tr>
<tr>
<td>Blush on CT scan (% of CT scan)</td>
<td>33 (21.9%)</td>
</tr>
<tr>
<td>Angiography</td>
<td>44 (24.7%)</td>
</tr>
<tr>
<td>Contrast extravasation on angiogram (% of angiography)</td>
<td>27 (61.4%)</td>
</tr>
<tr>
<td>Therapeutic angioembolization</td>
<td>30 (16.9%)</td>
</tr>
<tr>
<td>Indication for angiogram (multiple indications may apply) (% of angiography)</td>
<td></td>
</tr>
<tr>
<td>Ongoing hemorrhage</td>
<td>31 (70.5%)</td>
</tr>
<tr>
<td>Hemodynamic instability</td>
<td>30 (68.2%)</td>
</tr>
<tr>
<td>Blush on CT scan</td>
<td>18 (40.9%)</td>
</tr>
<tr>
<td>Large pelvic hematoma</td>
<td>14 (31.8%)</td>
</tr>
<tr>
<td>Fracture pattern</td>
<td>10 (22.7%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (2.2%)</td>
</tr>
</tbody>
</table>

Hemorrhage Management—Pelvic trauma—Results

<table>
<thead>
<tr>
<th>Table 6: Pelvic Fracture Hemorrhage Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td><strong>All Patients</strong> (N = 1,339), n (%)</td>
</tr>
<tr>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>No pelvic fracture intervention</td>
</tr>
<tr>
<td>Angioembolization alone</td>
</tr>
<tr>
<td>External fixator alone</td>
</tr>
<tr>
<td>Preperitoneal pelvic packing alone</td>
</tr>
<tr>
<td>Embolization + external fixator</td>
</tr>
<tr>
<td>Embolization + pelvic packing</td>
</tr>
<tr>
<td>External fixator + pelvic packing</td>
</tr>
<tr>
<td>Embolization + external fixator + pelvic</td>
</tr>
<tr>
<td>Packing</td>
</tr>
<tr>
<td>REBOA with or without any other</td>
</tr>
</tbody>
</table>
Hemorrhage Management—Pelvic trauma—Conclusions

• Mortality is high and the treatment paradigms vary
  • Multidisciplinary effort is key

• Opportunity for care improvement

• No clear relationship between the choice of hemorrhage control intervention used and the patient’s clinical status.
  • Lack of consensus by trauma surgeons as to the optimal algorithm for hemorrhage control interventions
Hemorrhage Management-Pelvic trauma—Limitations

• Observational study

• No data mentioned as to the mortality rates associated with each intervention for hemorrhage control

Emergency surgery updates


Emergency surgery updates


Does a dedicated EGS service change pt outcomes?—Background and Design

• Literature review to examine the impact of implementing dedicated emergency surgical services

• Several databases were queried looking at studies that assessed different care models and institutional factors affecting the delivery of emergency general surgery.

• 27 studies were evaluated; 744, 238 pts
Does a dedicated EGS service change pt outcomes?—Results

- Structural factors affecting care—Increased availability of experienced clinicians → reduced time to review and time to OR as well as reduced complication rates and length of stay
- Decreased emergency room stays for patients with surgical conditions.
- Mortality – decreased
- Length of Stay – decreased
- Financial Cost – decreased

Does a dedicated EGS service change pt outcomes?—Results

- No consensus on the optimal ACS; imp factors:
  - Senior surgeons on-site during office hours and taking calls from home but available to return to the hospital out of hours
  - Surgeons being cleared of elective commitments while on-call
  - 24-hour access to an emergency operating room
  - Minimize handovers
  - Rapid triage of patients
  - Early referrals to regional specialist centers.
Does a dedicated EGS service change pt outcomes?—Conclusions

- Improved care and decreased cost-delivery with a dedicated EGS service and provide a potential template for future planning, structuring, and delivering emergency general surgery on a broad scale.

Non-operative Management of Appendicitis
The NOTA Study—Background

• Acute appendicitis is one of the most common urgent surgical conditions

• Surgery has been the traditional standard of care recommendation

• Risk of major complications is low but there are risks associated with surgery—intraoperative complications, wound infection, post-operative adhesions and associated problems

• Perforated appendicitis is associated with increased morbidity and mortality

The NOTA Study—Objective

• To assess the safety and efficacy of primary antibiotic therapy suspected acute uncomplicated appendicitis and to monitor the long term follow-up of non-operated patients.

The NOTA Study—Design

• Single center (Italy), prospective observational trial

• Pts identified to have appendicitis based on H& P; labs and imaging.

• Pts determined to need immediate surgery were offered treatment with a 5-7 days course of amoxicilllin and clavulanic acid (1 grm TID)

• Pts who needed surgery at 7 day follow-up were termed failures and those who had recurrence of symptoms after this were termed recurrences

The NOTA Study—Design

• Pts with diffuse peritonitis, antibiotic allergy, previous antibiotic therapy, previous appendectomy, a positive pregnancy test, or inflammatory bowel disease were excluded

• Primary outcomes
  • Short-term efficacy of antibiotic tx
  • Long-term efficacy of antibiotic tx (f/u 7d, 15d, 6mo, 1yr and 2 yr
  • Safety of abx

The NOTA Study—Design

- Alvarado scores of \( \geq 5 \) and \(<10\) or AIR score of \( >2 \) and \(<11\) were eligible
The NOTA Study—Results

- In 2010 159 adult patients with suspected appendicitis underwent NOM with amoxicillin/clavulanate.
  - 116 patients (73%) were assessed by US
  - 27 patients (17%) were assessed by CT
- All 159 patients underwent NOM and received a course of amoxicillin/clavulanate

The NOTA Study—Results

• The short-term failure rate was 19/159 (11.9%)
  • Surgery provided

• After two years, the overall recurrence rate was 22/159 (13.8%)
  • 14/22 (63.6%) were successfully treated with a further cycle of amoxicillin/clavulanate.

• In total, 41/159 (25.8%) had either failure or a recurrence, of whom 27 (65.9%) needed surgery
  • Long term efficacy of Abx –83%

• Alvarado and AIR scores-only independent predictors of NOM failure.

The NOTA Study—Results

• No major side effects or complications noted with antibiotic therapy
• Pain was minimal by days 5 and 7
• Mean length of stay for non-operative patients was 0.4 days
• Most recurrences were seen within 6 months
• Mean sick leave was 5.8 days after Abx and 10 days after surgery

The NOTA Study—Conclusions

• Results suggest that non-operative management of healthy patients with uncomplicated, non-perforated acute appendicitis is safe and effective

• In this study US was most commonly used to diagnose appendicitis, unclear how these results would be applied to clinical practices more commonly using CT

The NOTA Study—Limitations

- Select pt population
- Scoring system used (Alvarado) over-predicts appendicitis in females
- Type of surgery not described
- Outcomes of surgery first pts not described
- Comparison between surgery first and Abx not described

Non-op management of appendicitis
The APPAC (Appendicitis Acuta ) trial—Background

• Previous trials have compared antibiotic therapy with appendectomy
  • Studies have had limitations

• INSERT TABLE 1

The APPAC trial—Objective

• To compare antibiotic therapy with appendectomy in the treatment of uncomplicated acute appendicitis confirmed by computed tomography (CT)
The APPAC trial—Design

- Multicenter, open-label, noninferiority RCT
- Conducted from 11/2009-6/2012 in Finland
- Patients were randomly assigned to early appendectomy or antibiotic treatment
  - Ertapenem (1 g/d) for 3 days followed by 7 days of oral levofloxacin (500 mg once daily) and metronidazole (500 mg 3 times per day)
  - Open appendectomy
- 1-year follow-up
The APPAC trial—Design

• Primary outcomes:
  • Successful completion of an appendectomy
  • Discharge from the hospital without the need for surgery and no recurrent appendicitis during a 1-year follow-up period

The APPAC trial—Results

- Enrolled 530 patients aged 18 to 60 years with uncomplicated acute appendicitis confirmed by a CT scan.
  - 273-Surgery
    - 1 canceled appendectomy—sx resolved
  - 257-Antibiotic
    - 70 pts (27.3%) required appendectomy during 1 year follow up (72.7% no surgery)
      - 15 (5.8%) during init. hospitalization
      - 58 (82.9%) had uncomplicated appendicitis
      - 7 (10%) had complicated appendicitis

The APPAC trial—Results

- Pts who underwent delayed appendectomy experienced complication rate of 7% compared to 20.5% for pts who underwent immediate surgery
- 4 (1.5%) tumors identified on final path
- No intra-abdominal abscess or other major complications associated with delayed appendectomy
- Did not demonstrate non-inferiority

The APPAC trial—Results

Table 3. Secondary Outcomes in the Appendicitis Acuta (APPAC) Trial

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Surgical Group (n = 273)</th>
<th>Antibiotic Group (n = 257)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall complication rate, % (95% CI)</td>
<td>20.5 (15.3-26.4)</td>
<td>2.8 (1.0-6.0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Surgical site infections by type, No.</td>
<td>24</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Organ space</td>
<td>1</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Deep Incisional</td>
<td>4</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Superficial</td>
<td>19</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Incisional hernias, No.</td>
<td>2</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Abdominal, incisional pain, or obstructive symptoms, No.</td>
<td>23</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Length of primary hospital stay, median (25th-75th percentile), d</td>
<td>3.0 (2-3)</td>
<td>3.0 (3-3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>VAS score, median (25th-75th percentile)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At discharge from the hospital</td>
<td>3.0 (2-4)</td>
<td>2.0 (1-2)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>At 1 wk</td>
<td>2.0 (1-3)</td>
<td>1.0 (1-1)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>At 2 mo</td>
<td>1.0 (1-1)</td>
<td>1.0 (1-1)</td>
<td>.40</td>
</tr>
<tr>
<td>Length of sick leave, median (25th-75th percentile), d</td>
<td>19.0 (14-21)</td>
<td>7.0 (7-12)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

The APPAC trial—Conclusions

• Among patients with CT-proven, uncomplicated appendicitis, antibiotic treatment did not meet the prespecified criterion for noninferiority compared with appendectomy

• Most patients randomized to antibiotic treatment for uncomplicated appendicitis did not require appendectomy during the 1-year follow-up period, and those who required appendectomy did not experience significant complications

The APPAC trial—Limitations

• Pts with appendicolith were excluded

• Open appendectomy performed primarily though not controlled
  • Laparoscopic specific outcomes not described

• High rate of complications in the surgery group

• Long hospital stay for surgery group

Management of perforated diverticulitis
Laparoscopic washout vs. Sigmoidectomy

• BACKGROUND
  • Common disease process
  • 8-35% present acutely with perforation
  • Laparoscopic peritoneal lavage has been suggested as an alternative to sigmoidectomy for patients with purulent peritonitis
    • Often the site of perforation has sealed

Laparoscopic washout vs. Sigmoidectomy

Objective

• The ladies trial (LOLA arm) aimed to assess the superiority of laparoscopic lavage compared with sigmoidectomy in patients with purulent perforated diverticulitis, with respect to overall long-term morbidity and mortality

Laparoscopic washout vs. Sigmoidectomy

**Design**

- Multicenter (34 centers across Europe)
- RCT, parallel-group
- Pts with general peritonitis and CT showing diffuse free intraperitoneal air or fluid eligible
  - Pts with shock, dementia, previous sigmoidectomy, pelvic irradiation, high-dose steroids and younger than 18 or older than 85 were excluded
- Randomized to laparoscopic lavage, Hartmann’s procedure or sigmoidectomy with primary anastomosis

Laparoscopic washout vs. Sigmoidectomy

Design

• All pts had a diagnostic laparoscopy to confirm diagnosis

• Primary endpoint: major morbidity and mortality within 12 months
  • Surgical re-intervention, abdominal wall dehiscence, abscess and urosepsis
  • Within 30d: MI, renal failure, respiratory insufficiency
Laparoscopic washout vs. Sigmoidectomy

Results

• 90 patients randomized between 7/2010-2/2013
• Enrollment terminated due to increased event rate in the lavage group
• Interim analysis major morbidity/mortality-35% (lavage) vs. 18% (sigmoidectomy)
  • Return to OR
    • 9 patients in the lavage group developed feculent peritonitis during recovery and 6 developed frank perforation

Laparoscopic washout vs. Sigmoidectomy

Results

• At 12 months: 30 (67%) of 45 patients in the lavage group and 25 (60%) of 42 patients in the sigmoidectomy group

• 4 patients had died after lavage and 6 patients had died after sigmoidectomy (p = 0.43)
### Laparoscopic washout vs. Sigmoidectomy

#### Results

<table>
<thead>
<tr>
<th>Event</th>
<th>Laparoscopic Lavage (n=46)</th>
<th>Sigmoidectomy (n=42)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short-term serious adverse events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>2 (4%)</td>
<td>1 (2%)</td>
<td>0.6237</td>
</tr>
<tr>
<td>Surgical reintervention</td>
<td>9 (20%)</td>
<td>3 (7%)</td>
<td>0.1230</td>
</tr>
<tr>
<td>Abscess with drainage</td>
<td>9 (20%)</td>
<td>0</td>
<td>0.0027</td>
</tr>
<tr>
<td>Fascial dehiscence</td>
<td>0</td>
<td>3 (7%)</td>
<td>0.1046</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0</td>
<td>1 (2%)</td>
<td>0.4773</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>6 (13%)</td>
<td>2 (5%)</td>
<td>0.1955</td>
</tr>
<tr>
<td>Renal failure</td>
<td>2 (4%)</td>
<td>2 (5%)</td>
<td>0.9207</td>
</tr>
<tr>
<td>Long-term serious adverse events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>2 (4%)</td>
<td>5 (12%)</td>
<td>0.1875</td>
</tr>
<tr>
<td>Surgical reintervention</td>
<td>13 (28%)</td>
<td>5 (12%)</td>
<td>0.1156</td>
</tr>
<tr>
<td>Abscess with drainage</td>
<td>2 (4%)</td>
<td>2 (5%)</td>
<td>0.9207</td>
</tr>
<tr>
<td>Fascial dehiscence</td>
<td>5 (11%)</td>
<td>5 (12%)</td>
<td>0.4359</td>
</tr>
<tr>
<td>Sigmoid carcinoma</td>
<td>5 (11%)</td>
<td>2 (5%)</td>
<td>0.3047</td>
</tr>
<tr>
<td>Recurrent diverticulitis</td>
<td>9 (20%)</td>
<td>1 (2%)</td>
<td>0.0315</td>
</tr>
<tr>
<td>Composite primary outcome (major morbidity or mortality at 12 months)</td>
<td>30 (67%)</td>
<td>25 (60%)</td>
<td>0.5804</td>
</tr>
</tbody>
</table>
Laparoscopic washout vs. Sigmoidectomy

Conclusions

• Laparoscopic lavage is not superior to sigmoidectomy for the treatment of purulent perforated diverticulitis

• No reduction in morbidity or mortality at 12 months

• Laparoscopic lavage resulted in a higher acute re-intervention rate without increased mortality

• Failure to identify Hinchey IV and underlying colorectal cancer accounted for most of the lavage failures
  • Imaging/diagnostic improvements needed

The Scandinavian Diverticulitis trial—Background

- Resection for perforated diverticulitis has a high morbidity and mortality rate
- Laparoscopic lavage has been reported as feasible and safe in cohort studies
  - Studies affected by selection bias
- This trial followed the previously reported European trial
Laparoscopic lavage vs. Resection

Objective

- Compare the outcomes from laparoscopic lavage with those for colon resection for perforated diverticulitis
  - Severe post-op complications within 90 days

Laparoscopic lavage vs. Resection

Design

• Multicenter, 21 centers in Sweden and Norway
• RCT
• 2/2010-6/2014
• Patients with suspected perforated diverticulitis, a clinical indication for emergency surgery, and free air on an abdominal computed tomography scan were eligible
Laparoscopic lavage vs. Resection

Design

• Pts with peritonitis and perforated diverticulitis were assigned to undergo laparoscopic peritoneal lavage or colon resection

• Primary outcome: was severe postoperative complications within 90 days
  • Complications requiring re-intervention, organ dysfunction, death

• Secondary outcomes included other postoperative complications, reoperations, length of operating time, length of postoperative hospital stay, and quality of life

Laparoscopic lavage vs. Resection

Results

- 509 patients screened, 415 were eligible and 199 were enrolled (after diagnostic laparoscopy)
  - Laparoscopic peritoneal lavage-101
  - Colon resection- 98
- Patients with fecal peritonitis underwent resection
  - 15 patients in the laparoscopic lavage
  - 13 in the colon resection
- Patients with a pathology requiring treatment beyond that necessary for perforated diverticulitis were excluded

Laparoscopic lavage vs. Resection

Results

• Severe post-op complications seen in 31% of lavage group and 26% of resection group (p = 0.53)

• Mortality between groups at 90 days was similar between groups

• The reoperation rate was significantly higher in the lavage group 20% vs. 6% (p = 0.01)
Laparoscopic lavage vs. Resection

Results

- The length of operating time was significantly shorter (72 min vs. 149 p < 0.01) and blood loss (3 mL vs. 175; p < 0.01) was significantly less in the laparoscopic lavage group.

- The length of postoperative hospital stay and quality of life did not differ significantly between groups.

- 4 sigmoid carcinomas were missed with lavage.

Laparoscopic lavage vs. Resection
Conclusions

- Patients with likely perforated diverticulitis and undergoing emergency surgery, the use of laparoscopic lavage vs primary resection did not reduce severe postoperative complications and led to worse outcomes in secondary end points.

- Findings do not support laparoscopic lavage for treatment of perforated diverticulitis.

Laparoscopic lavage vs. Resection Limitations

• Potential selection bias due to randomization after diagnostic laparoscopy
• Under powered to detect harm from laparoscopic lavage
• Patients with chronic illnesses excluded
  • Generalizability?
Biliary Pancreatitis and Timing of Cholecystectomy
The PONCHO trial—Background

• Even though there are recommendations for same admission cholecystectomy in gallstone pancreatitis, many clinicians opt for an interval approach (wait 6 weeks)

• Evidence to support same-admission cholecystectomy is poor

• Concerns exist about an increased risk of cholecystectomy-related complications with this approach due to increased procedural difficulty from pancreatitis related inflammation and edema

The PONCHO trial—Objective

• Compare same admission versus interval cholecystectomy for patients with mild acute gallstone pancreatitis
  • Within 3 days of randomization vs. 25-30 days after randomization

• Hypothesis: same-admission cholecystectomy would reduce the risk of recurrent gallstone-related complications without increasing the difficulty of surgery

• Did not control for ERCP/sphincterotomy

The PONCHO trial—Design

- Multicenter—23 sites in the Netherlands
- RCT, parallel-group, superiority trial
- Enrolled patients admitted with a first episode of gallstone pancreatitis from 12/2010-8/2013
- Excluded severe pancreatitis based on persistent organ failure >48 hours and CT findings, when available, of necrosis or fluid collections
- Enrolled on admission and assigned to one of the study arms 48 hours prior to anticipated discharge.

The PONCHO trial

- Mild pancreatitis defined
  - C-reactive protein concentration less than 100 mg/L
  - No opioid analgesics
  - Tolerate a normal oral diet
- No ongoing alcohol misuse
- Generally healthy

The PONCHO trial—Design

- Primary endpoint—gallstone related complications
  - Acute readmission for recurrent pancreatitis
  - Cholecystitis
  - Cholangitis
  - Obstructive choledocholithiasis needing ERCP
  - Billiary colic

- Co-Primary endpoint—mortality w/in 6 mo of rndm.

- Secondary endpoints—difficulty of cholecystectomy, conv. to open, and hospital LOS
The PONCHO trial—Results

- 266 pts enrolled
  - 129-same admission surgery
  - 137-interval cholecystectomy

- No differences in number of pts who had pre-randomization ERCP

- 17% of pts in the interval group suffered a gallstone related complication vs. 5% in the same admission surgery group
  - Of those that had same admission surgery complications arose after cholecystectomy and w/in 3 wks of d/c

The PONCHO trial—Results

• No difference in difficulty, conversion to open, cystic duct leak or bleeding (1 per group)

The PONCHO trial—Conclusions

• Same admission cholecystectomy for gallstone pancreatitis results in decreased readmission for gallstone related complications and suggests few complications

• Sphincterotomy does not appear to provide a protective effect against gallstone related complications though cholecystitis and biliary colic were included in this group

The PONCHO trial—Limitations

• Number of CBD injuries is not discussed
• Study not powered to show a difference in procedure related complications

Questions & Discussion
Audience response question

1. A 30 year old male is the unrestrained driver involved in a head on motor vehicle crash at highway speeds. He suffers multiple pelvic fractures, a liver laceration and significant blood loss. According to the PROPPR trial the best way to provide initial volume resuscitation for hemorrhage control is:
   a. Crystalloid fluids only
   b. 1:1:2 ratio infusion of plasma:platelets:RBC
   c. 1:1:1 ratio infusion of plasma:platelets:RBC
   d. Resuscitate based on Hgb and INR results
Audience response question

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Audience response question

1. A 25 year old female presents to the ED with right lower quadrant abdominal pain. CT imaging shows acute, non-perforated appendicitis. According to the AAPAC trial is this patient a candidate for non-operative management?

   a. True
   b. False
Audience response question

1. A 25 year old female presents to the ED with right lower quadrant abdominal pain. CT imaging shows acute, non-perforated appendicitis. According to the AAPAC trial is this patient a candidate for non-operative management?

   a. True
   b. False
1. A 45 year old male is currently being managed on the GI service with his first attack of gallstone pancreatitis. According to the PONCHO trial he would had a decreased risk of complications if cholecystectomy is delayed 6 weeks.

   a. True
   b. False
Audience response question

1. A 45 year old male is currently being managed on the GI service with his first attack of gallstone pancreatitis. According to the PONCHO trial he would have had a decreased risk of complications if cholecystectomy is delayed 6 weeks.
   
   a. True
   
   b. False
Thank you
ABC score

- 1 Point each for:
  - Penetrating mechanism
  - ED SBP < 90 mmHg
  - ED HR > 120
  - Positive FAST exam

- Scores > 2 are likely to require MT (sensitivity 75-80%; Specificity 67-88%)

Hinchey classification

- Perforation grade