Diagnosis and Management of Malignant Pleural Effusions

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Disclosures

• Consultant agreements with Olympus America and VIDA Diagnostics
• Site primary investigator for PulmonX industry-sponsored trial

“... as we know, there are known knowns; there are things we know we know. We also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns – the ones we don’t know we don’t know.”
- Donald Rumsfeld

Johari Window

- Known to Self
- Not Known to Self
- Known to Others
- Not Known to Others

Open
Blind
Hidden
Unknown
Based on the CXR findings, what is the most appropriate initial diagnostic step?

A. Navigation bronchoscopy  
B. CT guided TTNA  
C. EBUS TBNA  
D. U/S guided thoracentesis  
E. PET-CT scan  

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**Guidelines**

1. Adequate tissue should be obtained to accurately define the histologic type and perform molecular analysis when applicable. (ACCP, ESMO, NCCN, NICE)

2. Biopsy the pathologic site that would confer the highest stage, i.e. to biopsy a suspected metastasis. (e.g. pleural effusion M1a rather than a pulmonary lesion) (NCCN)

*Concomitant staging is preferential because it avoids additional biopsies or procedures.*
8th IASLC Lung Cancer Staging Classification

Epidemiology

- 126,825 admissions for MPE in the United States in 2012
  - Healthcare Cost and Utilization Project-National Inpatient Sample (HCUP-NIS)
- Mean age = 68.0 years (IQR 58.4-77.2)
- 55.8% female

<table>
<thead>
<tr>
<th>Primary Malignancy</th>
<th>Total</th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>37.8%</td>
<td>32.4%</td>
<td>44.5%</td>
</tr>
<tr>
<td>Breast</td>
<td>15.2%</td>
<td>26.8%</td>
<td>0.4%</td>
</tr>
<tr>
<td>GI</td>
<td>11.0%</td>
<td>8.1%</td>
<td>14.5%</td>
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<tr>
<td>Gynecologic</td>
<td>9.0%</td>
<td>16.1%</td>
<td>0%</td>
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<td>Hematologic</td>
<td>11.2%</td>
<td>9.1%</td>
<td>13.8%</td>
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<tr>
<td>Other</td>
<td>22.2%</td>
<td>14.0%</td>
<td>32.5%</td>
</tr>
<tr>
<td>Unknown</td>
<td>11.2%</td>
<td>12.2%</td>
<td>11.3%</td>
</tr>
</tbody>
</table>

Pleural Fluid

• 5-20 mL of pleural fluid
• 5-10 L of flow / day
• >75% of fluid absorbed through parietal pleura
• Normal fluid absorption can increase 20-30×


Case Presentation #2

You plan to perform an U/S guided thoracentesis. On further history, the patient is on warfarin for prior PE, but is clinically asymptomatic. What is the most appropriate diagnostic step?

A. Navigation bronchoscopy
B. Percutaneous TTNA
C. EBUS TBNA
D. U/S guided thoracentesis
E. PET-CT scan
You plan to perform an U/S guided thoracentesis. On further history, the patient is on warfarin for prior PE, but is clinically asymptomatic. What is the most appropriate diagnostic step?

A. Navigation bronchoscopy  
B. Percutaneous TTNA  
C. EBUS TBNA  
D. U/S guided thoracentesis  
E. PET-CT scan  
F. Reverse anticoagulation then U/S guided thoracentesis  
G. Refer to IR for thoracentesis

### Complications of TTNA

<table>
<thead>
<tr>
<th>Complications</th>
<th>SIR / ACR$^1$</th>
<th>Core$^3$</th>
<th>FNA$^4$</th>
<th>TTNA$^5$</th>
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</thead>
<tbody>
<tr>
<td>Overall</td>
<td>38.8%</td>
<td>24.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PTX</td>
<td>12.45%</td>
<td>25.3%</td>
<td>18.8%</td>
<td>15.0%</td>
</tr>
<tr>
<td>PTX w/ Intervention</td>
<td>2.15%</td>
<td>5.6%</td>
<td>4.3%</td>
<td>6.6%</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>18.0%</td>
<td>6.4%</td>
<td>2.0%</td>
<td></td>
</tr>
<tr>
<td>Hemoptysis</td>
<td>1.2%</td>
<td>4.1%</td>
<td>1.7%</td>
<td></td>
</tr>
</tbody>
</table>

$^1$ Meta-analysis  
$^2$ Core: 32 studies, 8,133 procedures  
$^3$ FNA: 17 studies, 4,620 procedures  
$^4$ 2006 data from 2 databases for CA, FL, MI, and NY  
$^5$ 19,885 patients  

### Complications of Guided Bronchoscopy

<table>
<thead>
<tr>
<th>Complications</th>
<th>AQuIRE$^1$</th>
<th>Mixed$^2$</th>
<th>R-EBUS$^3$</th>
<th>NAVIGATE$^4$</th>
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<tbody>
<tr>
<td>Overall</td>
<td>2.2%</td>
<td></td>
<td>7.9%</td>
<td></td>
</tr>
<tr>
<td>PTX</td>
<td>1.7%</td>
<td>1.5%</td>
<td>1.0%</td>
<td>4.9%</td>
</tr>
<tr>
<td>PTX w/ Intervention</td>
<td>0.7%</td>
<td>0.4%</td>
<td>3.2%</td>
<td></td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>0.2%</td>
<td></td>
<td>2.3%</td>
<td></td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>0.2%</td>
<td></td>
<td>0.6%</td>
<td></td>
</tr>
</tbody>
</table>

Complications of TBBx with Antiplatelet Agents

- Clopidogrel is a contraindication to TBBx
  - Bleed risk higher in clopidogrel vs. control group: 89% vs. 1.4%
  - Higher bleed risk for all categories of bleeding
    - Mild: 27% vs. 1.5%
    - Moderate: 34% vs. 1.5%
    - Severe: 27% vs. 0.3%

- Aspirin alone does not significantly increase bleed risk
  - Bleed risk similar to ASA (1.8%) vs. control group (2.3%)


Thoracentesis – Hemorrhage

- Risk of hemorrhage with thoracentesis is < 0.4%
  - No difference in hemorrhage based on INR or platelets
    - INR ≤ 2.0, 2.5, or 3.0 (No hemorrhage)
    - Platelets ≤ 100K, 50K, or 25K

- No difference in hemorrhage with transfusion of FFP or platelets
  - INR ≥ 1.6 and/or platelets ≤ 50K
    - No difference for transfusion-corrected versus uncorrected patients (0.4%)

- Small case series with low hemorrhage risk
  - Clopidogrel
  - Uremia

Patel and Jools. AJR Am J Roentgenol 2011;197:W164-8

Variability of Intercostal Artery Location

- Posteriorly, the intercostal artery is more exposed as it moves laterally
  - Degree of exposure correlates with age
- 86% of intercostal arteries were not “shielded” by the overlying rib
  - Measured at 3 positions along the back to xilla (133 points on 50 patients)

Intercostal Arteries are Not Straight

<table>
<thead>
<tr>
<th>Tortuosity</th>
<th>Description</th>
<th>Grade</th>
<th>Intercostal space n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear</td>
<td>0</td>
<td>32 (7.4)</td>
<td></td>
</tr>
<tr>
<td>Slight curve</td>
<td>1</td>
<td>152 (35.5)</td>
<td></td>
</tr>
<tr>
<td>Wavy</td>
<td>2</td>
<td>169 (39.4)</td>
<td></td>
</tr>
<tr>
<td>Sinuoidal</td>
<td>3</td>
<td>75 (17.5)</td>
<td></td>
</tr>
</tbody>
</table>

Collateral Branches

- Up to 80% of intercostal arteries may have a collateral branch
- Collateral branches tend to increase in size anteriorly

Avoiding Intercostal Vessels

- Rather than aiming superior to the rib, use ultrasound and aim for the middle of the intercostal space
Thoracentesis is performed without complication. Pleural fluid analysis is consistent with an exudate, but cytology does not demonstrate malignant cells. What do you recommend next?

A. Repeat thoracentesis  
B. Closed needle pleural biopsy  
C. CT guided FNA of the pleura  
D. Thoracoscopic pleural biopsy  
E. Navigation bronchoscopy and linear EBUS TBNA

Pleural Fluid for Diagnosis of MPE

- Pleural fluid sensitivity: 62-90%
- Utility of repeat thoracentesis decreases – diminishing returns
  - 1st sample: 65%
  - 2nd sample: 27%
  - 3rd sample: 5%
- At least 50-60 mL of fluid increases diagnostic yield, but ideal minimum volume for diagnosis is unclear
  - Swiderek: 60 mL and 150 mL outperformed 10 mL
  - Abouzghieb: 50 mL similar to "large volume" (mean 890 ± 375 mL)


Image courtesy of Alain Tremblay
Thoracoscopes

Rigid
• Richard Wolf, Karl Storz
• 7 mm diameter trocar sleeve
• 3 mm biopsy forceps
• Increased optical resolution
• Larger biopsies

Flex-Rigid
• Olympus
• 5 mm diameter trocar sleeve
• 2 mm biopsy forceps
• Increased maneuverability
• Smaller chest wall incision
• Grip same as bronchoscope
Rigid vs. Semi-Rigid Thoracosopes

- Larger and deeper biopsies for rigid > cryoprobe > flex-rigid
- Multiple series demonstrate similar diagnostic yields
  - Studies had few mesotheliomas (highest 30%)
  
Dhooria, et al. Respir Care 2014;59(5):756-764

Pleural Biopsy > Pleural Fluid

- Pleural Biopsy Options
  - Closed Needle Biopsy
  - Transthoracic Needle Aspiration
  - Medical Thoracoscopy
  - VATS

<table>
<thead>
<tr>
<th>Disease</th>
<th>Pleural Fluid</th>
<th>Closed Needle Biopsy</th>
<th>Thoracoscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung Cancer</td>
<td>55-60%</td>
<td>60% (↑ w/ U/S)</td>
<td>90-95%</td>
</tr>
<tr>
<td>Mesothelioma</td>
<td>30-70%</td>
<td>40%</td>
<td>&gt; 90%</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>&lt; 50%</td>
<td>80%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Koegelenberg and Diacon. Respirology 2011;16:738-746
Case Presentation #4

Repeat thoracentesis reveals malignant cells. IHC staining is TTF -, napsin A -, P63 (+), and P40 (+), suggestive of squamous cell carcinoma.

Which of the following would you request?

A. Limited panel of molecular markers: EGFR, ALK, KRAS
B. Broad molecular marker profiling with NGS
C. PD-1
D. Biomarkers have little utility in this setting
E. Refer to Oncology

Common IHC Markers for Lung Cancers

<table>
<thead>
<tr>
<th>TTF-1</th>
<th>Napsin A</th>
<th>CK7</th>
<th>CK20</th>
<th>P63</th>
<th>CK5/6, CK903</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-small cell</td>
<td>100%</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>May have focal CD99</td>
</tr>
<tr>
<td>Small cell</td>
<td>100%</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Squamous cell</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</tbody>
</table>

1. Thyroid metastasis can be TTF-1+ but are distinguished by thyroglobulin. Other adenocarcinoma metastases are usually TTF-1-.
2. Renal cell carcinoma, melanoma, squamous lymphoma, and Ewing's. There may be variably expressed in small cell carcinoma, but negative staining helps narrow differential diagnosis.
3. Melanoma and granulocytic sarcoma may be difficult to distinguish from primary lung lymphoma with focal intense CD20 expression in this diagnostic setting.
4. Metastatic prostatic adenocarcinoma may be difficult to distinguish from primary lung lymphoma; other tissues (e.g., renal cell carcinoma, mesothelioma, melanoma) may have focal positivity for TTF-1.


Adequacy for Molecular Marker Testing

- Testing for molecular markers has a high success rate in lung parenchyma, lymph nodes, and pleural biopsies

- Some sources are less successful
  - BAL, pleural fluid: fewer malignant cells
  - Bone: secondary to the acidification required in specimen processing

<table>
<thead>
<tr>
<th>Mutation</th>
<th>Lung</th>
<th>Lymph Node</th>
<th>Pleura</th>
<th>Bone</th>
</tr>
</thead>
<tbody>
<tr>
<td>EGFR</td>
<td>94%</td>
<td>97%</td>
<td>96%</td>
<td>83%</td>
</tr>
<tr>
<td>ALK</td>
<td>91%</td>
<td>94%</td>
<td>97%</td>
<td>78%</td>
</tr>
<tr>
<td>KRAS</td>
<td>92%</td>
<td>93%</td>
<td>92%</td>
<td>86%</td>
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</tbody>
</table>


Next Generation Sequencing for EGFR

- NGS (aka massively parallel sequencing) can simultaneously detect multiple point mutations but are not consistently recommended in practice guidelines. (recommended by NCCN)

- Ex) 48 BAL and pleural fluid samples from EGFR+ patients confirmed by reaction

<table>
<thead>
<tr>
<th>Sequencing</th>
<th>NGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>36 cases with 0.3% to 9% neoplastic cells</td>
<td>18%</td>
</tr>
<tr>
<td>12 cases without evidence of tumor</td>
<td>0%</td>
</tr>
</tbody>
</table>

Case Presentation #5

IHC testing confirms lung primary adenocarcinoma, EGFR(+) with exon 19 mutation. The patient has ECOG 2 performance status. There is initial reduction in tumor size with erlotinib therapy. The patient remains symptomatic from the pleural effusion. What palliative intervention would you recommend?

A. Repeat thoracentesis
B. Tunneled indwelling pleural catheter
C. Chest tube with talc pleurodesis
D. Thoracoscopy with talc pleurodesis
E. Refer to Palliative Care for hospice

Palliation Options

• Noninvasive palliation
• Recurrent thoracentesis
• Tunneled indwelling pleural catheter
• Pleurodesis
  • Chest Tube Stomy
  • Poudrage / Insufflation

Natural History of MPE

• Asymptomatic effusions often stay small
  • No progression in small, asymptomatic effusions (n=14)
  • Median radiographic follow-up: 98 days
  • Median survival: 128 days

• Symptomatic effusions usually rapidly recur
  • 94 patients with symptomatic MPE treated with thoracentesis drainage
  • 90 (95.7%) had a recurrence < 30 days
  • Mean time to symptomatic recurrence: 4.2 days

Predicting Prognosis for Patients with MPE

- **TIME3:** intrapleural urokinase prior to pleurodesis for septated MPE
  - Prospective, double-blind, 1:1 RCT
  - 71 subjects: 36 urokinase, 35 placebo
- **Exclusion:** expected survival < 4 weeks
- **No difference in co-primary outcomes:**
  - Dyspnea
  - Time to pleurodesis failure


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Predicting Prognosis for Patients with MPE

- 93% of subjects died within the 12 month follow-up period

  **Median Survival**
  - **Urokinase:** 69 days (IQR 24-123)
  - **Control:** 48 days (IQR 31-80)

27% died within 1 month
73% died within 3 months


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Poor Prognosis for MPE

- 789 patients from 3 international cohorts

  **Median Survival**
  - Overall: 4.5 months
  - Mesothelioma: 11.3 months
  - Breast/Gyn: 6.6 months
  - Lung: 2.5 months
  - Other: 2.5 months

L-E-N-T Prediction Score

- Factors independently associated with survival:
  - L DH (pleural fluid)
  - E COG performance status
  - N neutrophil : Lymphocyte (serum)
  - T tumor cell type
  - Effusion size
  - Serum NT-proBNP

Predicting Survival

Recurrent Thoracentesis

- Pleural effusions treated by aspiration alone are associated with a high rate of recurrence of effusion at 1 month so aspiration is not recommended if life expectancy is > 1 month.

Definitive Palliative Therapies

- Other than in patients with a very short life expectancy, small-bore chest tubes followed by pleurodesis are preferable to recurrent aspiration.
- In patients with good performance status, thoracoscopy is recommended for diagnosis of suspected malignant pleural effusion and for drainage and pleurodesis of a known malignant pleural effusion.
- Ambulatory indwelling pleural catheters are effective in controlling recurrent and symptomatic malignant effusions in selected patients.


Case Presentation #6

A TPC is placed without difficulty. While draining fluid after TPC insertion, the patient complains of chest pain. Post procedure CXR is performed.

What would you recommend?

A. Additional TPC drainage now
B. Attach TPC to suction via pleural drainage system
C. D/C patient and continue symptomatic drainage PRN

Bronchopleural Fistula vs. Pneumothorax ex vacuo

Hsia and Musani. Hosp Phys 2014; Vol 15, Part 1
Malignant Pleural Effusion Management Algorithm

TIME2: Definitive Palliation Options

Emerging Palliation Strategies

- Rapid Pleurodesis Protocol

- Silver Nitrate (AgNO3) Coated IPC
  - SWIFT: www.clinicaltrials.gov
Case Presentation #7
The patient has evidence of trapped lung but otherwise has relief of dyspnea with TPC drainage. How often do you recommend drainage?

A. Scheduled daily
B. Scheduled but not daily (e.g. q2 or q3 days)
C. PRN symptoms
D. Adjusted based on drainage volume

Drainage Frequency
- ASAP Trial: multicenter, RCT of TPC drainage frequency
  - Aggressive QD vs. standard QOD drainage
  - Primary outcome: incidence of autopleurodesis

![Graph: Aggressive drainage]
- more frequent pleurodesis
  - 47% vs. 24%, p=0.003
- shorter time to pleurodesis
  - 54 vs. 90 days, p<0.005

Big Picture: Are We Doing a Good Job?
Goals of Palliation for MPE
- Relieve Symptoms
- Minimize Hospitalization

How does our practice compare to guideline recommendations?
How well do we avoid readmissions?
Epidemiology

• 126,825 admissions for MPE in the United States in 2012
  - Health Care Cost and Utilization Project-Nationwide Inpatient Sample (HCUP-NIS)
• Mean age = 68.0 years (IQR 58.4-77.2)
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</tr>
<tr>
<td>Other</td>
<td>22.2%</td>
</tr>
<tr>
<td>Unknown</td>
<td>11.2%</td>
</tr>
</tbody>
</table>

• Median LOS: 5.5 days
  - 2.7-10.1 days (IQR)

• Inpatient Mortality: 11.6%

• Hospital Charges: $42,376
  - $21,618 - $84,679 (IQR)

Overuse of Repeat Thoracentesis?

• SEER-Medicare patient database

- Had Medicare A and B and no HMO within 12 mo before and after 1st claim of thoracentesis: n = 22,402

  - Did not have a second pleural procedure: 45%
    - n = 10,464 (46%)
  - Had a second pleural procedure within 14 d of first thoracentesis: n = 7,008 (32%)
    - Guideline consistent: 24%
      - n = 1,811 (24%)
    - Guideline inconsistent: 76%
      - n = 5,197 (76%)

- Had a second pleural procedure > 14 d of first thoracentesis: n = 5,492 (23%)

Distribution of Thoracentesis Numbers

AMPLE: Hospitalization for TPC vs. Pleurodesis

- Multi-center, international trial of TPC vs. Pleurodesis
  - 74 TPC
  - 72 Pleurodesis (talc slurry)
  - Exclusion: expected life expectancy < 3 months
- Primary outcome: total hospitalization days until death or 1 year


**AMPLE: Hospitalization for TPC vs. Pleurodesis**

<table>
<thead>
<tr>
<th></th>
<th>TPC (n=73)</th>
<th>Pleurodesis (n=72)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Hosp. Days</td>
<td>10 (3-17)</td>
<td>12 (7-21)</td>
</tr>
<tr>
<td>Initial Hosp. Days</td>
<td>1 (1-2)</td>
<td>3 (3-4)</td>
</tr>
<tr>
<td>MPE-Related Days</td>
<td>1 (1-3)</td>
<td>4 (3-6)</td>
</tr>
<tr>
<td>Non-MPE Days</td>
<td>5 (1-13)</td>
<td>7 (2-15)</td>
</tr>
</tbody>
</table>


**AMPLE: Hospitalization for TPC vs. Pleurodesis**

- Hospitalization days represented 7.1% of total trial days (median, IQR 1.9-28.3%)

Readmissions for MPE

- 7,965 hospitalizations in California for MPE from 2009-2011
  - Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUP) State Inpatient Database (SID)
  - ICD-9 codes used to track readmissions in patients with an index admission for MPE

### Disposition

<table>
<thead>
<tr>
<th>Disposition</th>
<th>7-Day Readmissions</th>
<th>14-Day Readmissions</th>
<th>30-Day Readmissions</th>
<th>60-Day Readmissions</th>
<th>90-Day Readmissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home - Routine</td>
<td>59.9%</td>
<td>25.9%</td>
<td>38.3%</td>
<td>52.5%</td>
<td>63.8%</td>
</tr>
<tr>
<td>Home Health Care</td>
<td>26.5%</td>
<td>11.3%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNF</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DNR</td>
<td>15.7%</td>
<td></td>
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<td></td>
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</table>

Yang, et al. Submitted for publication.
Factors Associated with Readmissions

<table>
<thead>
<tr>
<th>Patient Factors</th>
<th>Hospital Factors</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td>Hospital Size</td>
</tr>
<tr>
<td>Gender</td>
<td>Teaching Hospital</td>
</tr>
<tr>
<td>Race</td>
<td>Proportion of Minorities</td>
</tr>
<tr>
<td>Charlson Comorbidity Index</td>
<td>Hospital Type</td>
</tr>
<tr>
<td>Cancer Type</td>
<td></td>
</tr>
<tr>
<td>Median Income</td>
<td></td>
</tr>
<tr>
<td>Urbanicity</td>
<td></td>
</tr>
<tr>
<td>Payer Category</td>
<td></td>
</tr>
<tr>
<td>DNR Status</td>
<td></td>
</tr>
<tr>
<td>Disposition</td>
<td></td>
</tr>
<tr>
<td>Length of Stay</td>
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</table>

<table>
<thead>
<tr>
<th>Factor</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female Gender</td>
<td>0.78 (0.63-0.95)</td>
</tr>
<tr>
<td>Charlson Comorbidity Index</td>
<td>1.51 (1.15-1.99)</td>
</tr>
<tr>
<td>DNR Status</td>
<td>1.37 (1.03-1.84)</td>
</tr>
</tbody>
</table>

Hospital Variability in 30-Day Readmission Rates

- 313 Hospitals
- Excluded hospitals with < 5 MPE admissions/year

Thank you for your attention!

Conclusions

- MPE represents advanced disease with (generally) poor prognosis
- Palliative options are effective and should be selected based on the patient’s status and wishes
- Patients with MPE are frequently readmitted – this (probably) extends beyond use, selection, or failure of palliation methods and needs to be identified and prevented