Journal Club / Research Article Summary - (Adapted from Schultz Table)

Date: January 19th, 2011
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ARTICLE:
• Citation: Predicting Adverse Outcome in Patients with Acute Pulmonary Embolism: A Risk Score. Wicki J., Perrier A., Perneger TV, Bounnameaux H., Junod, AF. Thromb Haemost 2000; 84: 548-52.

• Country: Switzerland
• Funding Sources: None mentioned.

PURPOSE:
• Research Question(s): Is it possible to identify predictors of adverse events in patients with pulmonary embolism and to generate a simple risk score for use in clinical settings?

• Purpose Stated As: To identify low risk patient for ambulatory treatment by using a clinical predictor rule.

• Hypothesis: Generating a risk score based on easily available variables will be able to accurately discriminate between patients with pulmonary embolism at low and high risk of an adverse outcome (death, symptomatic recurrent PE, major bleed within 3 month follow up).

DESIGN:
• Study Design: Prospective cohort

• Dependent / outcome Variable(s): Adverse events (death from PE- confirmed by autopsy, symptomatic recurrent PE, major bleed [fatal, intracranial, intraocular, retroperitoneal, GI] or a fall of Hgb of 2g/dL or required RBC transfusion of 2 units) within 3 month follow up.

• Independent / research Variable: Clinical score → low risk or high risk category

SETTING / SUBJECTS:
• Research Setting: Single, University Hospital (in Geneva, Switzerland)

• Subjects: 296 adults
Study population: Adults diagnosed with PE by high probability VQ Scan, +DVT by ultrasound confirmed by lung scan, +pulmonary angiogram and those with high clinical suspicion and right heart strain on echo (n=2).

Inclusion / Exclusion criteria:
- Inclusion: Elevated D-dimer and +PE on diagnostic testing
- Exclusion criteria: none mentioned

Number (control / intervention groups): n=296→268 b/c some did not get ABG done and 1 pt did not have a BP done (lost 10% of sample size)

Demographics: (Table 1, page 549) Mean age 67.5 (range was 19-95)

Attrition: none

METHODS:

Interventions:
- Not well described: “Decisions regarding treatment were made by the patients’ attending physicians.”
- All patients were treated with anticoagulation - treatment was with unfractionated heparin, which was started INPATIENT (all patients were initially admitted).

Study Groups: A clinical score was calculated ranging from 0-7 points (Table 3).
- Multivariate predictors of adverse outcomes:
  - Cancer
  - CHF
  - Previous DVT
  - Systolic BP <100
  - PaO2 < 8 kP as
  - DVT on US

- Low risk (absence of an adverse event) = <= 2 pts (sensitivity 85%, specificity 73%, negative predictive value 97.7%).
  - n=180
  - 4 (2.2%) experienced an adverse outcome [2 had DVT→PE→death, 1 died from cancer, hypoxemic from PE→death]
- High risk if greater than or equal to 3 points.

Instruments:
- ROC (receiver operating characteristic) curve was used to determine “optimal cut off for discriminating between high and low risk categories.” AUC also used.

Data Collection:
Little information on data collection is provided. No detail as to the severity of CAD, COPD or CHF was given.
DATA ANALYSIS:
• **Statistics Used:**
  - Lots. Fischer, Multivariate logistic regression and prediction model

• **What, if any, confounding variables were controlled for / adjusted for:** None

RESULTS:
• **Brief answers to research questions:**
  - Low risk group included 67% of the total population and had an adverse event rate of 2.2%.
  - High risk group had an adverse event rate of 27.3%
  - The authors think that this rule does apply to all patients with a non-massive PE.

• **Additional findings:** None

• **Other possible explanation for findings:** None listed

• **Limitations:** The authors stated in the limitation portion: “In hospital management does not prevent the occurrence of adverse outcomes, but does allow for patients to be treated more rapidly.” But I think the real issue is:
  - The analysis was constructed with **dichotomous predictor variables** (present vs. absent) to facilitate its use in practice, therefore oversimplifying the way physicians interpret predictor variables.
  - Vague description of data collection and analysis will make this study difficult to repeat.
  - No discussion of medication complications (HIT)/non-compliance.
    - Who is measuring the PTT, How often? Who is administering the medication?

IMPLICATIONS FOR PRACTICE:
• **Applicable to this clinical practice:** Not Yet Applicable.

• **Feasibility (cost, resources, etc):** Yes

• **Clinically Relevant:** Yes

LEVEL OF EVIDENCE / DECISION FOR USE:
• **Background** Consider Replication (with stronger design) Ready for use

• **Level of Evidence:**
  - III Well-designed non-experimental studies