A Prospective Cohort Study Evaluating PAN-PROMISE, A Patient Reported Outcome Measure To Detect Post-ERCP Morbidity

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BACKGROUND

- **Post-ERCP Pancreatitis (PEP)** is the most common adverse event after ERCP and is defined by a physician-determined definition, the **Cotton Consensus Criteria** (CC-Criteria)

- That CC-Criteria has several limitations
  - **Post-Procedural pain is common post-ERCP**
  - Reduced specificity in patients with chronic abdominal pain
  - Difficult identifying whether a patient as prolonged solely due to PEP

- PAN-PROMISE, is a recently validated patient-reported outcome measure (PROM) for AP but has not been studied in the post-ERCP setting.

AIMS

To compare post-ERCP morbiditiy detected by PAN-PROMISE to physician determined outcomes defined by the CC-Criteria

METHODS

- **Design:** Prospective cohort study at the University of Pennsylvania and UCSF from 09/2020 to 08/2021
Inclusion Criteria: Planned cannulation of the bile duct and/or pancreatic duct and a major papilla with or without a prior sphincterotomy.
Exclusion Criteria: Surgical alteration of the major papilla, AP in the 7 days prior to ERCP.

Data Collection Timepoints: Pre-procedure (**PAN-PROMISE**, **SF-12**, **WPAIQ**), 48-72 hours (**PAN-PROMISE**), 7 days (**PAN-PROMISE**, **SF-12**, **WPAIQ**) and 30 days (**PAN-PROMISE**, **SF-12**, **WPAIQ**)

- **Outcome:** The primary outcomes were PEP and an Elevated-PROM, defined as a **change in the PAN-PROMISE at 7 days compared to baseline > 7.** (Cut-off determined by Receiver Operating Characteristics Analysis)

- **Statistical Analysis:** McNemar test used to compare discordance between CC-PEP and Elevated-PROM
- Pearson correlation coefficients used to evaluate association between QoL and Elevated-PROM
- Generalized Linear models used to evaluate direct and indirect costs
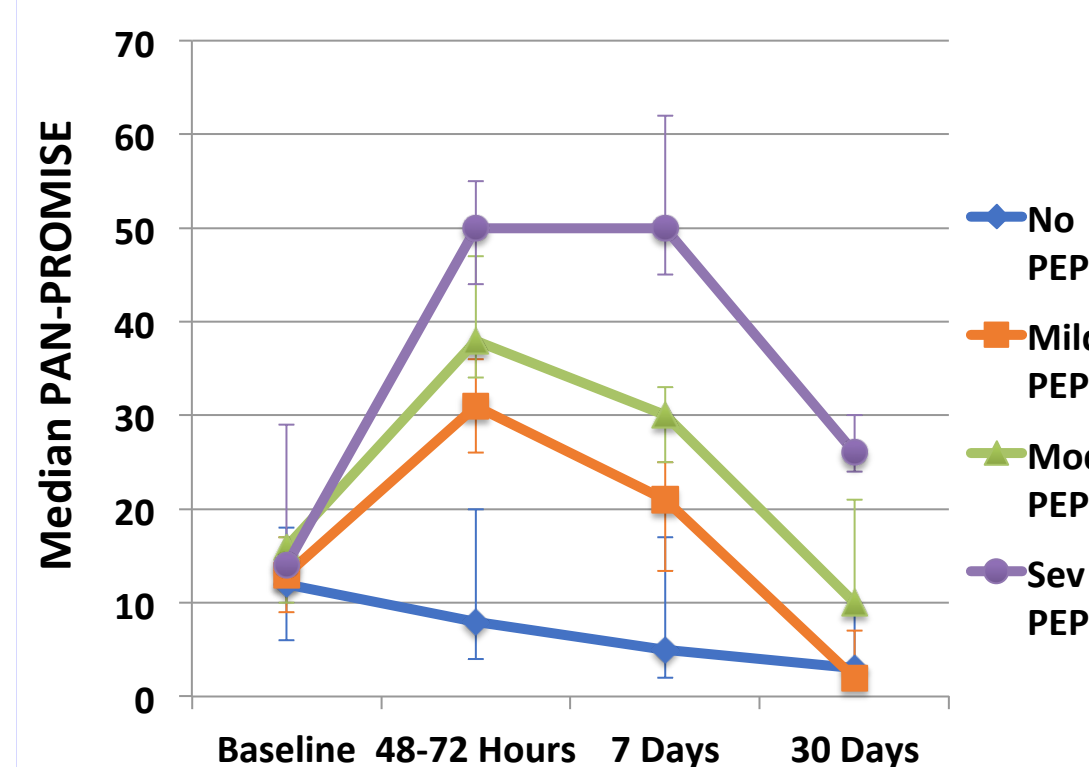
RESULTS

Figure 1. PAN-PROMISE scores for patients without PEP, with mild PEP, moderate PEP, and severe PEP.
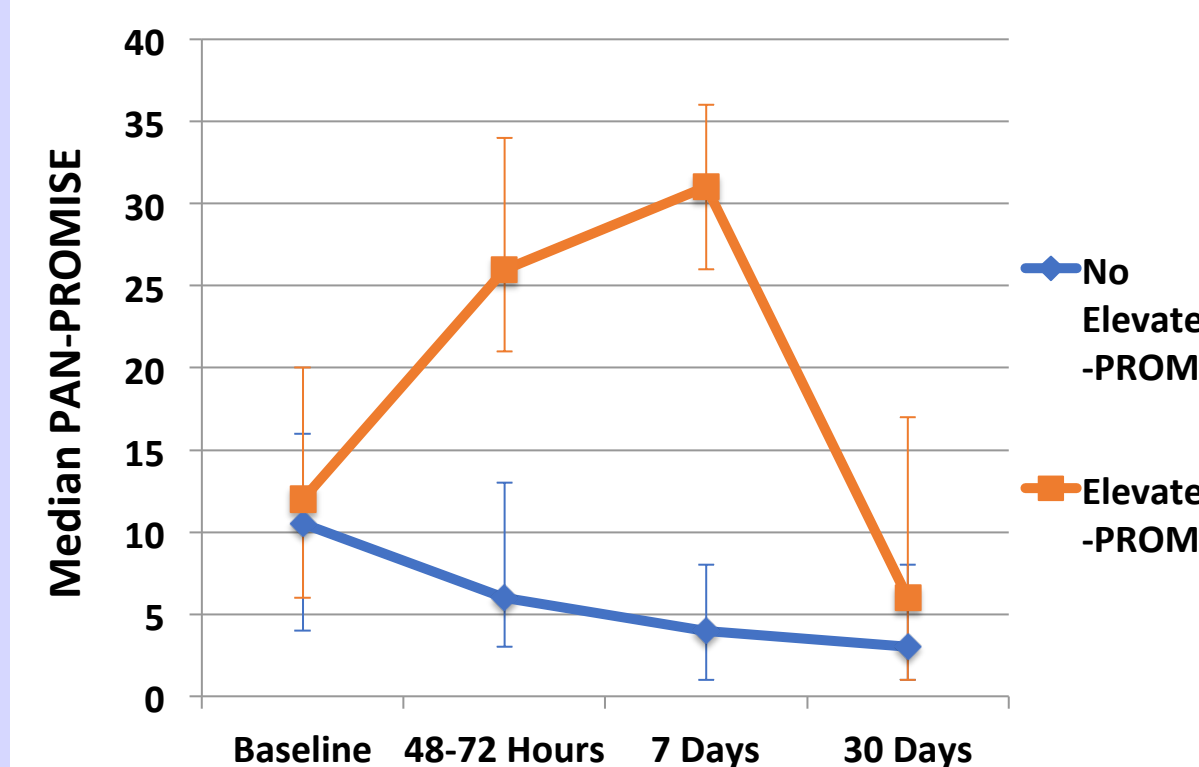

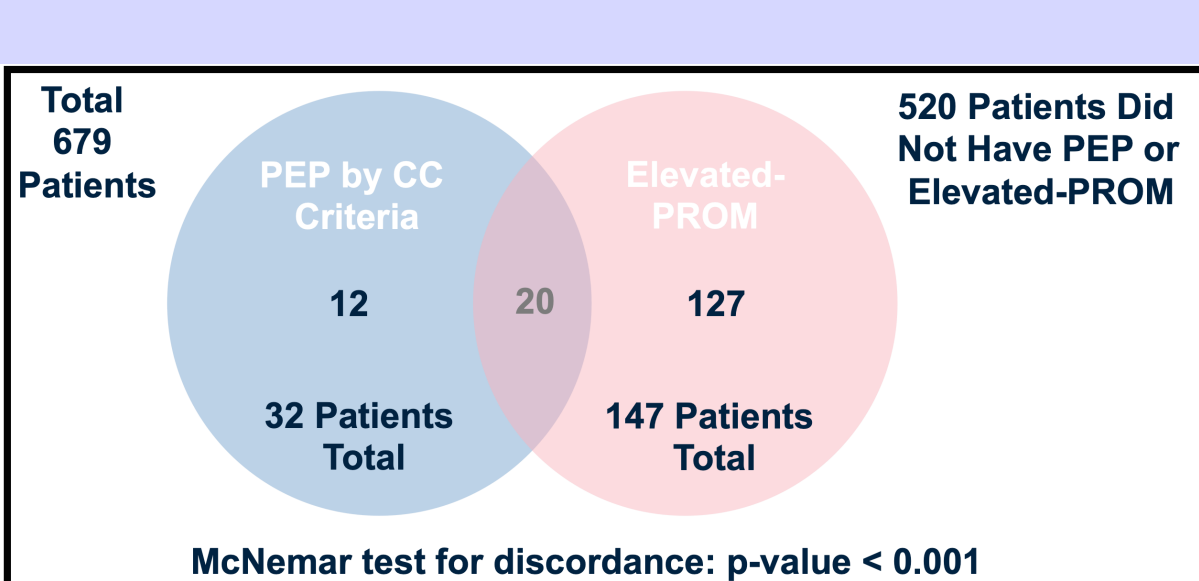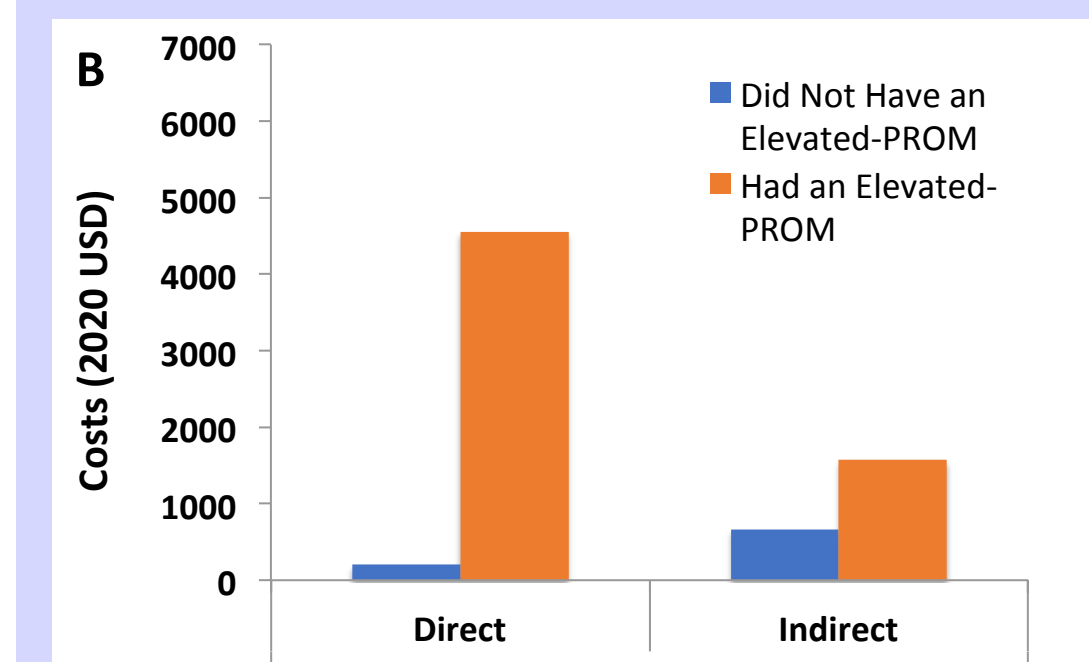Figure 2. PAN-PROMISE scores for patients without an elevated PROM and with an elevated PROM

Healthcare Costs at 30 days Post-ERCP
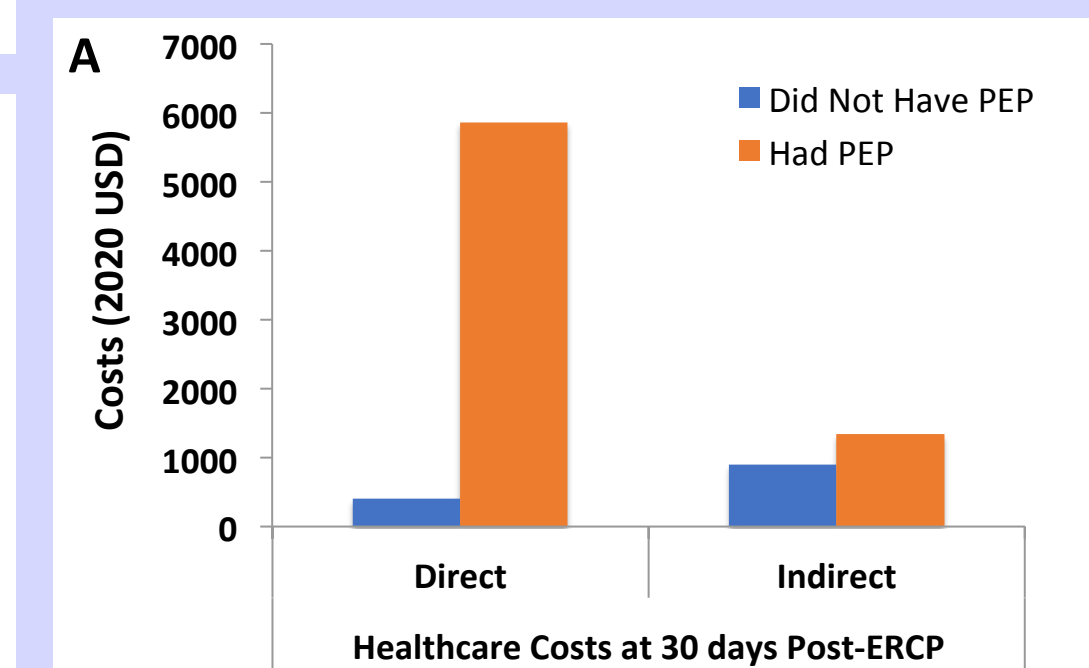
Figure 3. Venn Diagram comparing CC-PEP and Elevated-PROM

McNemar test for discordance: p-value < 0.001

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Figure 4. Healthcare Costs in PEP and Non-PEP Patients (A) and Elevated-PROM and Non-Elevated-PROM Patients (B)

SCAN ME

- 679 Pts enrolled. Median age was 63, 55% were male, most common indications for ERCP were CBD Stones (23%), Malignant biliary obstruction (31%) and OLT (12%). 94.8% received rectal indomethacin and 29.5% received aggressive hydration with LR.

- **32/679 patients (4.72%) developed PEP compared to 147/679 (21.6%) who had an elevated-PROM** (P<0.001, Figures 1-3)

- An Elevated-PROM strongly correlated with lower physical quality of life at 7 days (Mean 31.79 vs 48.79) and 30 days (41.7 vs 47.9) respectively

- Every 1-point increase in PAN-PROMISE at 7 days compared with baseline was associated with **$25.40 (95% CI, $6.40–$24.42)** in increased indirect health care costs and **$80.86 (95% CI, $49.73–$112.00)** in increased direct healthcare costs at 30 days post-ERCP (Fig 4)

- Patients with pancreatic cancer (**OR, 4.52; 95% CI, 1.68–10.74, P=0.002**), and primary sclerosing cholangitis (**OR, 1.79; 95% CI, 1.29–2.45, P=0.005**) had the highest odds of elevated PROM along with patients who had a SEMS placed. (**OR, 2.27; 95% CI, 1.25–4.17, P=0.007**)

CONCLUSIONS

1. A substantial number of patients experience significant morbidity after ERCP despite not developing PEP or other adverse events

2. Physician-determined criteria only captured 13.4% of patients who experience -significant post-ERCP morbidity.

3. Increased Post-ERCP symptoms associated with lower physical quality of life and higher healthcare costs.

4. Further prospective studies are needed to identify the reasons behind this symptom burden.

DISCLOSURES

The authors have no relevant financial or other relationships to disclose.

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