Evaluation of a novel method for measuring CEA levels from pancreas cyst aspirates

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Introduction

- Cyst fluid carcinoembroyonic antigen (CEA) and amylase help to discriminate neoplastic from benign pancreatic cysts.
- Often this evaluation is limited by the inability to obtain adequate fluid due to high fluid viscosity or limited volume of fluid in a small or septated cyst.
- A novel method is commercially available for measurement of CEA (RedPath Inc., Pittsburgh, PA) that requires 75µl of fluid compared to the amount previously required (1ml).
- The performance characteristics of this test have not been validated in the clinical setting.

Objective

- To examine the yield and diagnostic accuracy of CEA measurement of the commercial test compared to a standard academic institutional laboratory.

Methods

- Prospectively collected aspirates of pancreatic cyst of consecutive patients undergoing endoscopic ultrasound (EUS) with aspiration.
- All fine needle aspirates were performed with a 22g needle.

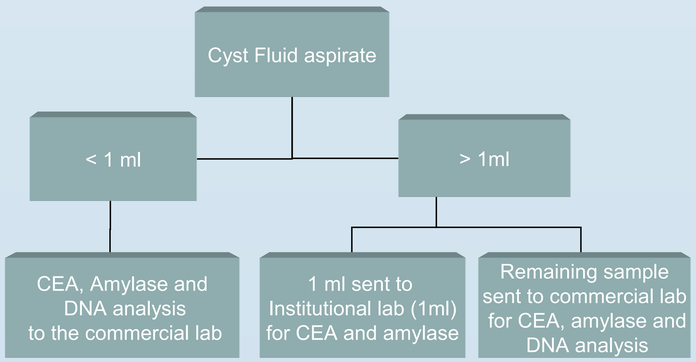

Figure 1. Algorithm for cyst fluid analysis

Methods

- Commercial lab used an internally-developed cyst fluid allocation protocol to optimize specimen utility.
- Immunodetection of CEA was done using Roche Modular E170 electrochemiluminescent immunoassay.
- Fluid dilution was not used except when sample volumes fell below 75 microliters.
- CEA measurement by the institutional lab was performed using similar assay but with a standard protocol requiring high fluid volume.

Results

- 13 patients underwent EUS FNA during the study period with 8 male (mean age 71.5 years) and 5 female(mean age 63.6 years).
- Cyst characteristics were described in Table 1.

Location	Body-3, Head-7, Uncinate-3
Mean cyst size	23.46 mm (11mm -40 mm)
Fluid quantity	Mean 5.5 (< 0.5 ml- 20 ml) Median- 3.5 ml
Mean CEA level	Institutional lab- 187.06 ng/ml Commercial lab-186.5 ng/ml

Table 1. Cyst characteristics

- CEA levels were available for all 13 patient samples sent to the commercial facility, the lowest volume from the commercial lab that yielded a CEA value was 50µl.
- In 2/13 (15%) there was insufficient fluid for CEA analysis in the standard laboratory, despite receiving the requisite 1ml.

Results

- Correlation with standard analysis showed low variability that did not affect interpretation of results. (Figure 2)
- When stratified by CEA levels greater than 192ng/ml, 192<CEA>5 or 5<CEA, there was discordance in only 1/13 patients.

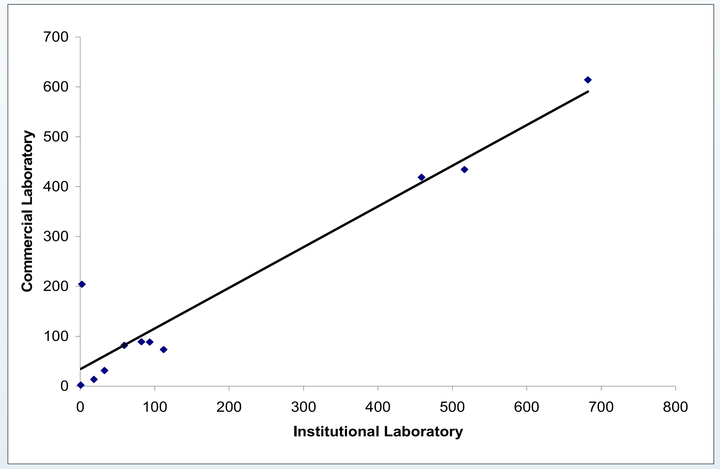

Figure 2. The Pearson correlation between CEA measurements was 0.957, demonstrating an excellent agreement.

Conclusion

- The novel commercial method of cyst fluid analysis allows for accurate measurement of cyst fluid CEA even on cyst fluid aspirates of less than 1ml, and potentially less than 100µl of fluid.
- This measurement tool increases the yield of EUS FNA for pancreatic cysts, particularly for those in whom cyst fluid volumes are small.
- By optimizing specimen handling, it is possible to satisfy information needs more effectively thereby contributing to more comprehensive and better diagnosis and management.