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IRB Proposal
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Title:
The Relationship Between Cystic Pancreatic Neoplasms and Location: Debunking the Myth

Study Purpose and Rationale:
Although there are multiple types of cysts that may develop in the pancreas, there are two that are both common among the cyst types but are also associated with either very high or very low malignant potential. Serous cystadenomas are generally known to be benign while mucinous cystadenomas have a variable but significant malignant potential (1). What is particularly interesting about these two cyst types is that over time, they have become known to have location preferences within the pancreas. In other words, the gastroenterological practicing community as well as the pre-existing literature both lay claim that mucinous and serous cystadenomas favor particular locations. More specifically, mucinous cystadenomas occur more frequently in the body and tail of the pancreas while serous cystadenomas occur more in the head (2)(3)(5). As a result of these associations, cysts that are found on imaging to be in the body and tail are treated more aggressively than those found to be in the head. This idea of a cyst type/location relationship has become accepted to the point that it is currently included in clinical knowledge databases used in everyday practice (4).

While the type/location relationship is found throughout the literature and is implemented in clinical practice, there are scattered studies describing anything from inverse relationships (serous cystadenomas being more likely to be found in the body and tail (6)) to no relationships (serous cystadenomas being found everywhere equally (3)). Furthermore, none of these studies have enrolled a large enough patient population or made the type/location relationship their primary endpoint.

The purpose of this study will be to evaluate serous and mucinous cystadenomas and determine if their classification correlates with their location within the pancreas.

1. Kim, S., Lee, J., et al. 2006. Macrocystic Neoplasms of the Pancreas: CT Differentiation of Serous Oligocystic Adenoma from Mucinous Cystadenoma and Intraductal Papillary Mucinous Tumor. AJR. 187.
2. Compagno, J. 1978. Mucinous Cystic Neoplasms of the Pancreas with Overt and Latent Malignancy (Cystadenocarcinoma and Cystadenoma). American Journal of Clinical Pathology. 69(6).
3. Compagno, J. 1978. Microcystic Adenomas of the Pancreas (Glycogen-rich cystadenomas). American Journal of Clinical Pathology. 69(3).
4. Khalid, A., McGrath, K. 2010. Pancreatic cystic neoplasms. Uptodate.com.
5. Takeshita, K. 2008. Differential Diagnosis of Benign or Malignant Intraductal Papillary Mucinous Neoplasm of the Pancreas by Multidetector Row Helical Computed Tomography: Evaluation of Predictive Factors by Logistic Regression Analysis. Journal of Computed Assisted Tomography. 32(2).
6. Malur, PR., Suranagi, VV., et al. 2009. Serous microcystic adenoma of the pancreas. Indian Journal of Pathology and Microbiology. 52(3).

Study Design and Statistical Procedures:
This is a retrospective cohort study that will look at approximately 100 patients with serous cystadenomas and 100 patients with mucinous cystadenomas. Most of these patients initially were found to have an incidental finding of a pancreatic cyst on either CT/MRI. Standard of care led them to have EUS (endoscopic ultrasound). From there, the location of the cyst was documented. Determination of the cyst type occurred through different methods. Patients that underwent EUS also had an FNA (fine needle aspirate) performed at the time of the procedure. In addition, they had serum tests (amylase, lipase, CA19-9) as well as tests on the FNA fluid (cytology, amylase, CEA). Those that were found to have a serous cystadenoma were managed expectantly. Those whose results were suspicious or more predictive of a mucinous cystadenoma underwent surgical resection with pathological examination of the specimen. Those patients could have had either serous or mucinous lesions.

Other information will also be collected: demographics (age at diagnosis, gender, race/ethnicity) as well as smoking/alcohol use, size of cyst, imaging modalities used, and *presumed* cyst type.

Analyses will be performed using statistical computer software. ANOVA and Chi-square tests will be implemented as well as general descriptive statistics.

Study Drugs or Devices: N/A

Study Questionnaires: N/A

Study Subjects:
Subjects will be chosen by cyst diagnosis. Based on sample size analysis, approximately 100 mucinous cystadenomas and 100 serous cystadenomas are needed for statistical power. These subjects have already undergone extensive, standard of care evaluation and management of their cysts, particularly EUS +/- surgical resection with pathological analysis.

Recruitment: N/A

Confidentiality of Study Data:
All patient data is from an existing EUS-findings database. Those findings along with surgical report/path, lab, imaging results, cytology reports, and demographics will be analyzed. All information will be de-identified for confidentiality purposes.

Potential Risks: N/A

Potential Benefits: N/A

Alternatives: N/A