Published in final edited form as:

Pancreas. 2013 April ; 42(3): 436–441. doi:10.1097/MPA.0b013e31826c711a.

SENSITIVITY OF ENDOSCOPIC ULTRASOUND, MULTIDETECTOR COMPUTER TOMOGRAPHY AND MAGNETIC RESONANCE CHOLANGIOPANCREATOGRAPHY IN THE DIAGNOSIS OF PANCREAS DIVISUM: A TERTIARY CENTER EXPERIENCE

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Abstract

OBJECTIVES—There are limited data comparing imaging modalities in the diagnosis of pancreas divisum. We aimed to: 1. Evaluate the sensitivity of endoscopic ultrasound (EUS), magnetic resonance cholangiopancreatography (MRCP) and multi-detector computed tomography (MDCT) for pancreas divisum. 2. Assess interobserver agreement (IOA) among expert radiologists for detecting pancreas divisum on MDCT and MRCP.

METHODS—For this retrospective cohort study, we identified 45 consecutive patients with pancreaticobiliary symptoms and pancreas divisum established by endoscopic retrograde pancreatography (ERP) who underwent EUS and cross-sectional imaging. The control group was composed of patients without pancreas divisum who underwent ERP and cross-sectional imaging.

RESULTS—The sensitivity of EUS for pancreas divisum was 86.7%, significantly higher than sensitivity reported in the medical records for MDCT (15.5%) or MRCP (60%) [$p < 0.001$ for each]. On review by expert radiologists the sensitivity of MDCT increased to 83.3% in cases where the pancreatic duct was visualized, with fair IOA ($\kappa = 0.34$). Expert review of MRCPs did not identify any additional cases of pancreas divisum; IOA was moderate ($\kappa = 0.43$).

CONCLUSIONS—EUS is a sensitive test for diagnosing pancreas divisum and is superior to MDCT and MRCP. Review of MDCT studies by expert radiologists substantially raises its sensitivity for pancreas divisum.

Keywords

Pancreas Divisum; Pancreatitis; Endoscopic Ultrasound; Magnetic Resonance Cholangiopancreatography; Endoscopic retrograde Cholangiopancreatography; Computer Tomography

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Results of this study were presented in part at Digestive Disease Week 2011, Chicago

Disclosure: The authors have no conflicts of interest or funding to disclose.

BACKGROUND

Pancreas divisum is the most common developmental variant of pancreatic anatomy and is found in approximately 3-15% of western population.¹ This variant is the result of a failure of the ventral and dorsal pancreatic anlagen to fuse during the fifth week of embryologic development. As a result, the dorsal duct drains most of the pancreatic glandular tissue via the minor papilla and the ventral duct drains the pancreatic head and uncinate process through the major papilla. This anatomic variant is thought to be benign in most patients; however there is a subgroup of patients in whom pancreas divisum may lead to recurrent bouts of acute pancreatitis or chronic pancreatitis.^{1,2} Cotton et al reported a 26% prevalence rate of pancreas divisum in patients with unexplained pancreatitis as compared to 3.6% in patients undergoing endoscopic cholangiopancreatography (ERP) for other indications.^{3,4} While the clinical significance of pancreas divisum has been a topic of great debate through the years, the preponderance of the current evidence points to a significant association between pancreas divisum and acute recurrent pancreatitis as well as chronic pancreatitis.^{5,6} Traditionally the diagnosis of pancreas divisum has been made during ERP; contrast injection in patients with pancreas divisum into the ventral duct shows a short ventral duct tapering terminally into side branches within the pancreatic head whereas ductography through the minor papilla demonstrates a patent dorsal system draining the pancreatic body and tail.¹ While ERP is the gold standard for the diagnosis of pancreas divisum and can serve as a platform for therapy; it has several drawbacks as a first line diagnostic test; as it is an invasive test requiring sedation and carries a 10-15% complications rate; with up to 10% of patients developing post-ERP pancreatitis.⁶⁻⁸

Given the drawbacks of ERP there has been significant interest in evaluating for structural causes of unexplained pancreatitis, and more specifically pancreas divisum, in a less invasive manner. Most of the published literature focuses on the use of cross-sectional imaging, in particular multi-detector computer tomography (MDCT) or magnetic resonance cholangiopancreatography (MRCP).⁹⁻¹³ Retrospective studies from expert centers have reported sensitivities of 60-73% for MRCP using ERP as a gold standard.^{11,12} For MDCT, a sensitivity and specificity of 90% and 97% respectively have been reported; however, in these studies all MDCT studies were performed at a single institution under a uniform protocol.⁹ The accuracy of these cross-sectional imaging modalities in routine clinical practice is unclear and may be lower than the above reported rates.^{12,14} In a recent retrospective study Carnes et al., found that pancreas divisum was reported on MRCP in 44% of patients who were eventually diagnosed with divisum by ERP at a tertiary referral center.¹⁴ Our anecdotal experience indicates that lower rates of divisum reporting reflects the fact that pancreas divisum may be considered a normal anatomic variant by radiologists.

The use of endoscopic ultrasonography (EUS), which allows detailed imaging of the pancreatic parenchyma and ductal system, for the diagnosis of pancreas divisum has been described. EUS has been reported to have a diagnostic accuracy of 97% with 95% sensitivity and 97% specificity for the diagnosis of pancreas divisum.¹² There is limited data on the relative diagnostic characteristics of these various nominally invasive modalities (EUS, MRCP, MDCT) in the evaluation of pancreas divisum with ERP as the gold standard in a single cohort of patients. Additionally, little data exists on the interobserver agreement among radiologists for identifying pancreas divisum on MDCT, when the study is obtained with non-pancreatic protocols versus dedicated pancreas protocol. Thus, the aims of this study were (i) to evaluate the sensitivity of EUS, MRCP and MDCT for identifying pancreas divisum in patients who underwent ERP and (ii) to assess interobserver agreement among radiologists for the diagnosis of pancreas divisum using cross-sectional imaging modalities.

METHODS

Patients

This study was conducted at Barnes Jewish Hospital/ Washington University in St Louis, a tertiary referral center. The institutional endoscopic database was used to identify patients diagnosed with pancreas divisum at ERP between January 2003 and October 2010. Consecutive patients age ≥ 18 years who underwent EUS at our institution and had at least one cross-sectional imaging study (MRCP or MDCT) performed within 6 months of the ERP available for review in the electronic medical record were included in the study. The electronic medical record was reviewed and all pertinent demographic (age, gender), clinical (presenting symptoms) and radiological data (MRCP and MDCT reports) were abstracted from the chart. The diagnosis of chronic pancreatitis was based on ERP findings (Cambridge score ≥ 3).¹⁵ The institutional review board of Barnes Jewish Hospital/ Washington University in St Louis approved this study.

ERP and EUS Examination

ERP and EUS exams were performed by one of five experienced biliary endoscopists. The diagnosis of pancreas divisum was suspected at ERP if cannulation of the major papilla revealed a short ventral pancreatic duct which did not cross the midline and was confirmed if cannulation of the minor papilla revealed a distinct dorsal pancreatic duct.

All EUS exams were performed with a linear array echoendoscope (GF-UC140P or GFUCT140; Olympus Medical Systems, Center Valley, PA). A standardized approach for diagnosing pancreas divisum was used by all endosonographers. Briefly, after passing the echoendoscope to the 2nd portion of the duodenum and visualizing the major papilla endosonographically, the balloon was inflated and imaging initiated. The ventral pancreatic duct and common bile duct ending at the level of the major papilla were visualized. The ventral pancreatic duct was then followed from the head of the pancreas to the body by gradually withdrawing the echoendoscope. If the ventral pancreatic duct could not be visualized or followed to the body of the pancreas (unable to trace the ventral pancreatic duct from the ventral to the dorsal anlage), pancreas divisum was suspected. This was confirmed endosonographically by visualizing the dorsal pancreatic duct from the minor papilla to the body of the pancreas. This usually requires torqueing of the echoendoscope clockwise and pulling the echoendoscope back to the level of the minor papilla.

Cross-Sectional Imaging

Results of cross-sectional imaging studies (MDCT, MRCP) were reviewed and presence or absence of pancreas divisum recorded from the report. All cross-sectional imaging studies were performed in the course of evaluation of unexplained foregut symptoms and/or pancreatic disease of unclear etiology. In order to assess for interobserver variability among radiologists and to account for the possibility that pancreas divisum may not have been reported by radiologists under the assumption that it is a benign anatomic “variant”, cross-sectional images from patients with pancreas divisum were reviewed by two radiologists, who were blinded to ERP results. Radiologists initially reviewed the studies to assess if the pancreatic duct could be visualized; in those cases when the duct was seen, ductal anatomy was described; with respect to presence or absence of pancreas divisum. Cross-sectional imaging studies from control subjects were added to the study set in order to avoid bias. The control group for this portion of the study comprised of subjects who had undergone ERP for the treatment of Sphincter of Oddi dysfunction (no evidence of pancreas divisum) at our institution during the study period and had MDCT/ MRCP images available for review in the electronic medical record. Patients with acute pancreatitis on cross-sectional imaging were excluded from this part of the study, as were patients who had undergone MDCT

without IV contrast administration or MRCP without gadolinium. Data pertaining to MDCT quality was abstracted, including section thickness and if oral contrast was administered. The MDCT and MRCP scans were then reviewed and classified into one of three categories: pancreas divisum present, normal pancreatic duct and pancreatic duct not visualized. Two expert radiologists, specializing in abdominal imaging; independently reviewed MDCT and MRCP studies for incomplete and complete pancreas divisum and were blinded to the ERP results.

Statistical Analysis—All grouped data are reported as mean and standard deviation. Test performance characteristics, including sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated for EUS, MRCP and MDCT using ERP as the gold standard. Inter-observer agreement was measured using Kappa statistic. The Kappa statistic was used to evaluate strength of agreement as follows: slight (Kappa value, 0 – 0.20), fair (Kappa value, 0.21– 0.40), moderate (Kappa value, 0.41– 0.60), very good (Kappa value, 0.61– 0.80), and excellent (Kappa value, 0.81–1.00).¹⁶ Students' T test and Chi-Square test were used for group comparisons. A “p-value” of <0.05 was required for statistical significance.

RESULTS

During the study period 5185 ERP's were performed and pancreas divisum was diagnosed in 184 (3.6%) cases. 45 patients with pancreas divisum (average age 53.8 ± 14.4 years), 32 female (71.1%), who underwent ERP as well as EUS and at least one cross-sectional imaging study were identified and included in the study. The indications for evaluation of the pancreatic duct were as follows: recurrent acute pancreatitis 26 (57.7%), unexplained pancreatic type abdominal pain 16 (35.6%), and chronic pancreatitis in 3 (6.7%) subjects. In addition to pancreas divisum, changes of chronic pancreatitis were seen on ERP $\pm$ EUS in 13 (28.9%) subjects. Pancreas divisum was initially diagnosed by EUS in 19 (42.2%) cases, MRCP in 9 (20%) cases and ERP in 17 (37.8%).

Sensitivity of EUS

Of the 45 subject with pancreas divisum, 39 were correctly identified by EUS; a sensitivity of 86.7% (figure 1). In 25 subjects EUS was performed prior to ERP and pancreas divisum was diagnosed in 21 (84.0%). Changes of chronic pancreatitis were observed on ERP and EUS in 3 of 6 the subjects in whom EUS was false negative. In subjects with chronic pancreatitis, by ERP criteria, the sensitivity of EUS for pancreas divisum was 76.9%. There were no complications related to EUS.

Sensitivity of MRCP

MRCP reports were available for review in 25 subjects; none of the studies were secretin enhanced (figure 2). Of the MRCP studies 18 were performed at our center and 7 were performed and interpreted at referring institutions. Pancreas divisum was reported as present in 15 cases; a sensitivity of 60%. Pancreas divisum was reported at a higher frequency when studies were performed and interpreted at the tertiary referral center compared to outside referring centers (72.2% vs. 14.3%, $p < 0.001$). Five patients who were diagnosed with chronic pancreatitis based on ERP findings underwent MRCP and pancreas divisum was noted in 80% of the studies.

Sensitivity Of MDCT Based On Retrospective Review Of Initial Reports

The reports of MDCT studies were available for 33 of the subjects; 8 of these were performed under pancreatic protocol. The presence of pancreas divisum was initially reported in 5 cases (figure 3). The overall sensitivity of MDCT for pancreas divisum was

15.2%. The sensitivity of pancreatic protocol MDCT studies for pancreas divisum was 37.5%; while MDCTs performed under non-pancreatic protocols had a sensitivity of 8% for pancreas divisum ($p=0.078$). Pancreas divisum was not noted in any of the studies performed at referring institutions. All 5 of the MDCT studies where pancreas divisum was identified on initial review were performed and interpreted at our institution. Of the 12 patients with chronic pancreatitis in whom MDCT reports were available for review, pancreas divisum was identified in 3 (25%).

Diagnostic Performance and Interobserver Variability of MRCP Interpreted by Expert Radiologists

The full MRCP studies were available for review in 15 subjects with pancreas divisum and were reviewed along with 16 studies from patients with no pancreas divisum [average age 53 ± 9.6 years, 12 (38.7% female)] on ERP and visible pancreatic duct on MRCP. All studies were performed with intravenous gadolinium contrast according to standard MRCP protocol. The pancreatic duct was visualized on all MRCPs. On review both observers correctly identified pancreas divisum in 9 of 15 cases (60%), there were 6 false negatives, and 1 false positive; giving MRCP a sensitivity of 60%, specificity of 93.8% and positive predictive value of 90% when all MRCP studies were considered together (table 1). No additional cases of pancreas divisum were identified on expert review of MRCP studies. Inter-observer agreement was fair, Kappa of 0.43.

Diagnostic Performance and Interobserver Variability of MDCT Interpreted by Expert Radiologists

The full MDCT studies were available for review in 20 subjects with pancreas divisum and were reviewed along with 28 studies from patients with no pancreas divisum [average age 57.2 ± 13.8 years, 25 (89.3% female)] on ERP and visible pancreatic duct on MDCT. The technical details of the MDCT studies are as follows: intravenous contrast was used for 48 (100%) of the studies, 14 (35%) of the studies were performed under pancreatic protocol, oral contrast was used in 2 (5%); the average section thickness was 3.5 ± 1.7 mm. The pancreatic duct could not be visualized on MDCT in 8 patients with pancreas divisum; who were excluded from further analysis in this portion of the study.

When the pancreatic duct was visualized (40 MDCT studies), both observers correctly identified pancreas divisum in 10 of 12 cases (83.3%), there were 2 false negatives, and 17 false positive; giving MDCT a sensitivity of 83.3% and positive predictive value of 37.0% when all MDCT studies were considered together (table 1). Inter-observer agreement was fair, Kappa of 0.34.

If only pancreatic protocol MDCT studies were considered ($n=14$) both observers correctly identified pancreas divisum in 7 of 7 cases (100%); there were no false negatives and 5 false positives. Thus, under pancreatic protocol MDCT had a sensitivity of 100%, and positive predictive value of 58.3% for pancreas divisum. The inter-observer agreement was excellent, Kappa of 1.0. MDCT performed under nonpancreatic protocol ($n=26$) had a sensitivity of 60% and positive predictive value of 20%; inter-observer agreement for detecting pancreas divisum on this group was poor (Kappa of 0.12).

DISCUSSION

Pancreas divisum is both a common congenital variant in pancreatic anatomy and a likely cause for acute and chronic pancreatitis in a proportion of the population.^{1,3} The diagnosis of pancreas divisum has traditionally been established by ERP; however in recent years noninvasive, cross-sectional imaging studies as well as EUS have emerged as alternative

modalities in evaluating patients with unexplained pancreaticobiliary symptoms for pancreas divisum. Our data demonstrate that EUS is a sensitive method for establishing the diagnosis of pancreas divisum correctly identifying pancreas divisum in 86.7% of cases. Additionally, in our series both MDCT and MRCP had a moderate sensitivity for identifying pancreas divisum when performed in routine practice; and in the case of MDCT the sensitivity was substantially improved when studies were reviewed by expert radiologists.

Overall, EUS appears to have moderate to high sensitivity for pancreas divisum and the results of our study are consistent with those reported previously. In a series of 36 patients, six of whom had pancreas divisum; Bhutani et al., observed that EUS had an overall accuracy of 80% for pancreas divisum.¹³ These authors defined pancreas divisum as being present by EUS if an image simultaneously demonstrating the portal vein, common bile duct and main pancreatic duct could not be obtained (a negative stack sign) with a radial EUS probe.¹³ In a later study, Lai et al., found EUS performed with a linear probe, to have an accuracy of 97% and sensitivity of 96% for pancreas divisum in a series of 162 patients, 22 of whom had pancreas divisum diagnosed by ERP. Pancreas divisum was diagnosed when the ventral pancreatic duct could not be followed from the major papilla to the body of the pancreas or crossed the ventral-dorsal anlage. However, 35 (21.6%) examinations with incomplete visualization were excluded from the analysis in this report. If these were classified as negative examinations, the sensitivity of EUS would have been 82%; similar to the current study.¹² In our study, the majority of false negative studies were in patients with evidence of advanced chronic pancreatitis on ERP; and we speculate that in the presence of chronic pancreatitis, dilated side branches, irregularity of the main pancreatic duct as well as calcifications and stones could interfere with the visualization of the duct.

We observed that sensitivity of 15.2% for MDCT studies performed in the course of routine clinical practice; with pancreas divisum being reported more frequently on studies performed at our tertiary care center. When MDCT studies were reviewed by expert radiologists, and the pancreatic duct was visualized, the sensitivity increased markedly, to 83.3% if all MDCT studies were considered and 100% for pancreatic protocol MDCT. Additionally, the interobserver agreement among radiologists for the detection of pancreas divisum was moderate if all MDCTs were considered and excellent for pancreatic protocol MDCT. It should be noted however, that the pancreatic duct could not be visualized on MDCT in 28.6% of patients with pancreas divisum; thus if these patients were included in the analysis the sensitivity of MDCT would have been adversely affected.

With respect to MRCP performed in the course of clinical practice, a sensitivity of 60% was observed, and as with MDCT pancreas divisum was reported significantly more frequently on studies performed at our center. However, expert review of MRCP studies did not have an impact on the sensitivity MRCP for identifying pancreas divisum; while interobserver agreement amongst radiologists was comparable to that of MDCT. These findings suggesting that in the case of MRCP technical limitations of the study rather than level of radiologist expertise is the underlying factor leading to missed cases of pancreas divisum on MRCP.

Although some early MRCP studies noted high accuracy rates, these studies were fraught with exclusions and verification biases in terms of the gold standard test used.¹⁷ However, recent studies have reported a more modest accuracy rate; similar to that observed in our study.^{11,14} Carens et al., observed a sensitivity of 44% for finding pancreas divisum on MRCP in patients referred to a tertiary center for the evaluation of pancreatic pathology.¹⁴ This study also demonstrates that studies performed at a tertiary referral center have a sensitivity of 60-70% versus 14-30% for MRCP's performed at referring institutions. Mosler et al., also reported a sensitivity and specificity of 73.3% and 98%, respectively, for

detection of pancreas divisum using secretin enhanced MRCP performed at a tertiary referral center.¹⁸ It should be noted that none of the MRCP studies in our series were secretin enhanced, which may have led to a decreased sensitivity for pancreas divisum. However, we believe that these results are representative of what is seen in practice, as our anecdotal experience indicates that secretin is rarely used to enhance MRCPs due to cost as well as concern for allergic reaction to secretin.

Variable results regarding the sensitivity of MDCT for detection of pancreas divisum have been reported. In an early study, Soto et al., reported a high sensitivity (>90%) and specific (95%) for the diagnosis of pancreas divisum.⁹ However a later report from the same group found the sensitivity of MDCT to be 60%.¹⁹ Anderson et al., reported the sensitivity of MDCT to be 60-80% for divisum on review by expert radiologists.¹⁹ These discrepancies in the performance of MDCT may relate to differences in setting of the study (tertiary vs. community center) and MDCT protocols used. The results of the present study support the notion that interpretation by a sub-specialized radiologist yields the highest accuracy; with no of the cases of pancreas divisum being noted on initial review of MDCT studies performed at referring institutions. Moreover, our results highlight the importance of selecting the appropriate MDCT protocol for evaluating pancreatic ductal anatomy; with pancreatic protocol MDCT having markedly better performance characteristics for identifying pancreas divisum than routine single phase of contrast and thicker slice acquisitions. These factors are likely responsible for the high false positive rate of non-pancreatic protocol MDCT for pancreas divisum; we speculate that signal averaging due to slice thickness was a significant factor in limiting the radiologist's ability to evaluate ductal anatomy. Interobserver agreement for detecting pancreas divisum also paralleled this superior trend observed in the performance characteristics for pancreatic protocol MDCT.

When compared to cross-sectional imaging, EUS has definite advantages in addition to its ability to detect pancreas divisum. While not addressed in our current study, EUS has been shown to potentially identify small lesions, which may be missed on cross-sectional imaging.¹² Additionally, EUS allows for tissue acquisition during the exam; which is of particular importance, as neoplasm obstructing the proximal pancreatic duct can lead to a ductographic finding of pseudodivisum; and these lesions are often seen only on EUS.^{12,20} However, these advantages have to be tempered against the invasive nature of EUS, cost and inconvenience of sedation, which is required for EUS.

Our study does have several limitations. Firstly, the order in which studies were performed was not uniform, and the diagnosis of pancreas divisum was initially established by ERP (the gold standard) in a minority of patients. While this may have led to some verification bias, 62.2% of the cases of pancreas divisum were initially noted on EUS (19) or MRCP (9). All procedures were performed using a linear array echoendoscope and hence this study does not assess the accuracy of radial endosonography for detecting pancreas divisum. Another limitation is that radiologic studies (MDCT and MRCP) were conducted under a variety of protocols; therefore the results do not reflect the accuracy of optimized cross-sectional imaging studies (i.e. pancreatic protocol MRCP and MDCT). However, we believe that the variable conditions may better reflect a routine practice setting in which patients are often imaged in the emergency room or prior to knowledge that the pancreas is the organ of interest. Finally, all EUS exams were performed by expert endosonographers at a tertiary care hospital, which is a tertiary referral center and hence this may limit the generalizability of our results.

In conclusion, linear array EUS appears to be a sensitive minimally invasive modality for detecting pancreas divisum in patients who are being evaluated for acute recurrent, idiopathic and chronic pancreatitis. Cross-sectional imaging may under-report pancreas

divisum in routine clinical practice. When cross-sectional imaging is performed for the evaluation of pancreaticobiliary pathology, the indication should be discussed with the radiologist and either an MRCP or pancreatic protocol MDCT should be performed for best accuracy. However, even in optimal conditions, EUS is able to identify pancreas divisum in a majority of patients who have negative findings on cross-sectional imaging and therefore, EUS should play a pivotal role in evaluating for pancreas divisum in patients with unexplained pancreaticobiliary symptoms when nonendoscopic imaging studies are negative; prior to ERP.

Thus, EUS should be considered as an important diagnostic modality in the evaluation of patients with unexplained pancreatitis; particularly when cross-sectional imaging studies are unrevealing. Future large, prospective trials are required in order to assess the potential of EUS in this group of patients.

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Figure 1.

EUS image of complete pancreas divisum, with the dorsal pancreatic duct opening into the minor papilla and the ventral pancreatic duct (dashed arrow) opening into the common bile duct (CBD) seen in the same plane.

Figure 2.

MRCP coronal reconstruction showing complete pancreas divisum. The dorsal duct opens anterosuperior to the common bile duct through the minor papilla (solid arrow). The ventral duct draining through the major papilla (dashed arrow).

Figure 3. MDCT showing complete pancreas divisum, with the dorsal pancreatic duct opening into the minor papilla (white arrows) and the dorsal pancreatic duct draining into the major papilla (black arrow).

Table 1

Performance Characteristics of MRCP and MDCT for Pancreas Diviosm, When Pancreatic Duct was Visualized

	MRCP (n=32)	All MDCT (n=40)	Pancreatic Protocol (n=14)	Non Pancreatic Protocol (n=26)
Sensitivity	60.0%	83.3%	100.0%	60.0%
Specificity	93.8%	39.3%	28.6%	42.9%
Positive Predictive Value	90%	37.0%	58.3%	20.0%
Negative Predictive Value	71.4%	84.6%	100.0%	81.8%
Accuracy	77.4%	52.5%	64.3%	46.2%