Original article

The efficacy and safety of single-session endoscopic ultrasound-guided fine needle aspiration and endoscopic retrograde cholangiopancreatography for evaluation of pancreatic masses

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Abstract

Background/Aims: There have been limited studies evaluating single-session endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) and endoscopic retrograde cholangiopancreatography (ERCP) for evaluation of pancreatic masses. The aim of this study was to determine the safety of single-session EUS-FNA and ERCP, and to compare the diagnostic accuracies of cytodiagnosis by EUS-FNA, ERCP, and their combination.

Methodology: A total of 100 patients (61 male and 39 female) with pancreatic masses were prospectively enrolled. All patients underwent single-session EUS-FNA and ERCP. The main outcome measurement was frequency of post-procedural complications. Another measurement was diagnostic accuracy of cytodiagnosis by EUS-FNA, ERCP, and their combination.

Results: Procedure-related pancreatitis occurred in 10 patients (10%), but all patients were conservatively managed. No other types of complications were observed. Cytodiagnosis by EUS-FNA was significantly superior to ERCP in sensitivity (88.2% vs 55.3%) and accuracy (91.0% vs 66.0%). In patients with a pancreatic head mass, 3 cases of false negative EUS-FNA were positive on ERCP. The combination of EUS-FNA and ERCP improved accuracy (93.8% vs 87.5%), and sensitivity (91.2% vs 82.4%) compared with EUS-FNA alone. By contrast, in the subgroup of the pancreatic body or tail mass, the combination of EUS-FNA and ERCP did not improve cytodiagnosis compared to that with EUS-FNA alone.

Conclusions: Single-session EUS-FNA and ERCP appears to be as safe as performing each procedure separately. EUS-FNA should be considered the principal procedure for cytodiagnosis. ERCP has only a complementary role in patients with pancreatic head mass.

Keywords: Endoscopic Retrograde Cholangiopancreatography, Endosonography, Endoscopic Ultrasound-Guided Fine Needle Aspiration, Pancreatic Neoplasms

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is one of the most commonly used techniques for the treatment of pancreatic disorders. ERCP allows for a diagnosis to be established and the obstruction relieved at the same time. In addition, brushing the tumor or aspiration of pancreatic/bile juice during ERCP offers samples for cytodiagnosis that can aid in the diagnosis of pancreatic tumors. However, the sensitivity of cytodiagnosis during ERCP is not sufficiently high. For example, previous studies reported the sensitivity of 46.9-70.0%[1,2,3]. In contrast, in recent years, endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) has been widely accepted as an effective modality to obtain tissue samples for the diagnosis of pancreatic masses. In terms of the cytodiagnosis, higher diagnostic accuracy of 78.0-95.0% has been reported for EUS-FNA[4].

In patients with pancreatic disorders requiring biliary drainage as a treatment of biliary stricture, biliary stent placement may hamper detailed visualization of tumors by subsequent endoscopic ultrasonography (EUS). On the other hand, performing EUS-FNA first enables prompt diagnostic imaging and pathologic examinations of the tumor. However the obstruction may remain untreated until another day of ERCP, indicating the delay of starting adequate therapies. In this context, combining EUS-FNA and ERCP into a single session is a desirable procedure that enables pathological diagnosis of a tumor and drainage of the obstructed duct without delay. Nevertheless, only a few prospective studies of single-session EUS-FNA and ERCP have been reported[5,6].

The aim of this study was to evaluate the efficacy and the safety of the combined procedure in a prospective study of 100 patients. Another purpose of this study was to compare the diagnostic accuracy of cytodiagnosis between EUS-FNA,

ERCP, and their combination in the same patient set.

Methodology

A total of 100 consecutive patients were included in this prospective study conducted from June 2009 to October 2011 at our hospital (trial registration: The University Hospital Medical Information Network [UMIN] Clinical Trials Registry, Number: UMIN000004119). For inclusion in this study patients had to (i) have solid masses in the pancreas, (ii) be twenty years old or more, and (iii) be in need of a pathological diagnosis, i.e., prior to treatment. The suspicious pancreatic masses were detected by computed tomography (CT) and/or transabdominal ultrasonography. Thin-slice multidetector helical CT scanning and/or abdominal magnetic resonance imaging was also performed at our institution before single-session EUS-FNA and ERCP. Exclusion criteria were as follows: patients with cystic mass, Karnofsky performance status < 50%, active infection, patient with inaccessible papilla Vater due to altered anatomy, bleeding tendency (platelets < 50000/mm^3, or prothrombin time < 50%), severe complication such as liver cirrhosis or heart disease, active concomitant malignancy, and otherwise being inappropriate for entry into this study according to the investigator's judgment. This study was approved by institutional review board in our institution (approval no. 682). Written informed consent was obtained from all patients.

EUS-FNA and ERCP were performed during the same session under intravenous anesthesia with pethidine hydrochloride and diazepam. All procedures were performed in the prone position. EUS-FNA was performed by a linear array echoendoscope (GF-UCT240; Olympus, Tokyo, Japan) with an ultrasound scanning system (prosound α-10; Hitachi-Aloka Medical Co, Tokyo, Japan). A 19-, 22-, or

25-gauge needle (ECHO-19, ECHO-3-22, ECHO-25; Cook Medical, Tokyo, Japan) was used in EUS-FNA. The needle size was selected by the principal endosonographer. The specimens were immediately assessed for adequacy by the cytotechnologist and were then stained with Hemacolor (Merck KGaA, Darmstadt, Germany) for examination to establish a tissue diagnosis. Puncture was repeated if the on-site cytotechnologist judged that the specimen was inadequate for the following pathological evaluation. After EUS-FNA, the patient underwent an ERCP for tissue sampling with a JF260V duodenoscope (Olympus, Tokyo, Japan). Biliary stent placement was also performed if required. For selective cannulation into the pancreatic/bile duct, a conventional cannulation technique via major papilla was used. If it proved difficult to access the pancreatic/bile duct by selective cannulation, a precut sphincterotomy was performed. Cell samples for cytodiagnosis were collected by brushing with RX cytology brushes (Boston Scientific Japan, Tokyo, Japan) and/or by aspiration of pancreatic/bile juice through ERCP catheters. Although brushing to collect cell samples was attempted in all cases, sample collection by brushing could not be completed due to anatomical and/or technical problems in some cases. In these cases, the pancreatic juice and/or bile was collected for cytologic evaluation. The total procedure time was calculated from the insertion of the first instrument to the removal of the last instrument. The combined procedure was considered as accomplished when the scheduled examination was completed and the tissue sample was acquired by both EUS-FNA and ERCP.

We determined whether the pancreatic mass was malignant or not by surgically resected specimens or by long-term follow up of > 6 months. In patients who did not undergo surgical resection, malignancy was considered to be present if the primary tumor was enlarged or if metastatic disease arose during the follow-up period.

Pancreatitis as a post-procedural complication was defined if abdominal pain

and a greater than threefold elevation of the upper limit of serum amylase were observed 24 hours after the endoscopic procedure. The severity of complications was graded by criteria defined by Cotton et al[7]. To evaluate the safety of single-session EUS-FNA and ERCP, possible risk factors of complication were also investigated. Clinically relevant risk factors were dichotomized and compared with each complication variable in a univariate analysis by chi-square test. The sensitivity, specificity, positive and negative predictive values, and accuracy were determined for ERCP, EUS-FNA and a combination of the two methods. Cytodiagnosis was defined as accurate if the pancreatic mass was correctly judged as cancer or non-cancer. The exact 95% confidence intervals (95% CI) of frequencies were calculated by means of the binomial distribution. Differences in diagnostic yields between pairs of the three methods were identified by using the McNemar test, and p values < 0.05 were considered statistically significant. Statistical analysis was performed by JMP software, version 7.

Results

A total of 100 patients (61 male and 39 female) who underwent single-session EUS-FNA and ERCP were analyzed. Clinical characteristics of the patients at entry are summarized in Table 1. The mean age of the patients was 64.4 years (rage: 24-87 years). Final diagnosis was confirmed by surgery in 36 patients and long-term follow-up in 64 patients. The median length of the follow-up of the patients was 299 days. Of the 100 patients, the final diagnosis was pancreatic cancer in 74 patients, neuroendocrine tumor in 9, chronic pancreatitis in 5, autoimmune pancreatitis in 4, serous cyst adenoma in 3, gastrointestinal stromal tumor in 1, cholangiocarcinoma in 1, metastatic pancreatic tumor from renal cancer in 1, intraductal papillary mucinous carcinoma in 1, and

pancreatic lipoma in 1 (Table 2). The mean size of the pancreatic masses was 27.0 mm in maximum diameter.

The number of needle passes in EUS-FNA varied according to the sample adequacy evaluated by cytotechnologist, with a mean of 3.3 ± 0.9 (range: 1-7 times). In ERCP, deep cannulation into the pancreatic duct was successfully performed in 98 of the 100 patients (98.0%). Deep cannulation into the bile duct was intended in 74 patients, since the bile duct involvement was suspected, or anatomical information of the bile duct is required for the following surgery. Cannulation into the bile duct was successfully performed in 72 patients (97.3%). Of these, a precut sphincterotomy was required to access the pancreatic/bile duct in 7 patients. We intended to complete the combined procedure within 70 minutes, but it took more than 70 minutes in 25 patients. The procedure time of EUS-FNA was 29.0 ± 9.5 minutes (range: 13-52 minutes) and that of ERCP was 29.1 ± 14.4 minutes (range: 5-69 minutes). The total procedure time of EUS-FNA plus ERCP was 61.0 ± 15.8 minutes (range: 27-97 minutes). Deep cannulation into the targeted duct failed in 5 patients. Additionally, tissue samples could not be acquired by ERCP in 4 patients. Cytodiagnosis by ERCP was performed in the remaining 91 patients (brushing of pancreatic duct in 39, brushing of bile duct in 11, brushing of both pancreatic and bile duct in 5, and collection of pancreatic and/or bile juice in 36 patients). By contrast, tissue sample was obtained by EUS-FNA in all patients. Consequently, the accomplishment rate of the combined procedure was 91% (91/100 patients). In terms of the adequacy of the samples for pathological assessment, 78 of the 91 samples (85.7%) obtained by ERCP was adequate, whereas 99 of the 100 samples (99.0%) obtained by EUS-FNA was adequate.

Sedation-ratated events such as hypoxemia were not observed. Procedure-related pancreatitis occurred in 10 patients (10%). Of these, 7 patients had

mild pancreatitis, and the other 3 patients had moderate pancreatitis. All patients were conservatively managed, and no surgical intervention was required to treat the complications. No other types of complications, such as bile leak, were observed. Univariate analysis of 14 potential predictors revealed that only female gender was a risk for post-procedural complications (Table 3).

Diagnostic accuracy of cytodiagnosis for cancer by endoscopic procedure is shown in Table 4. The sensitivity of EUS-FNA was 88.2%, specificity was 100%, and accuracy was 91.0%. On the other hand, the sensitivity of ERCP was 55.3%, specificity was 100%, and accuracy was 66.0%. Cytodiagnosis by EUS-FNA was significantly superior to ERCP in sensitivity and accuracy. The combination of EUS-FNA and ERCP improved the sensitivity (94.0%) and accuracy (94.0%) of the cytodiagnosis. However, these values were not statistically significant compared with those of EUS-FNA alone.

The analysis for diagnostic accuracy based on the tumor location is shown in Table 5. In patients with a pancreatic head mass, 3 cases of false negative EUS-FNA were positive on ERCP . Therefore, in the subgroup of the pancreatic head mass, the combination of EUS-FNA and ERCP improved accuracy (93.8% vs 87.5%) and sensitivity (91.2% vs 82.4%) compared with EUS-FNA alone. In contrast, in the subgroup of patients with pancreatic body or tail masses, the combination of EUS-FNA and ERCP did not lead to improved cytodiagnosis compared with EUS-FNA alone.

Discussion

To our knowledge, only one article has described a prospective study of single-session EUS-FNA and ERCP. Tarantino *et al*. reported that 72 patients underwent EUS and ERCP in a single session, and EUS-FNA was performed in 25 of the 72 patients[5]. Therefore, this is the largest prospective study regarding the combined

procedure.

Ross *et al*. retrospectively analyzed 114 patients with obstructive jaundice due to presumed pancreatic malignancy who underwent single-session EUS-FNA and ERCP. Complications occurred in 12 of the 114 patients (10.5%), and 6 of them had pancreatitis[8]. Mergener *et al*. published a case of post-procedural pneumoperitoneum who underwent ERCP and EUS-FNA tandemly[9]. Di Matteo *et al*. reported two cases of biliary leakage after EUS-FNA and ERCP in a same day[10]. Consequently, pneumoperitoneum and biliary leakage, in addition to pancreatitis, are possible post-procedural complications after the combined procedure. In our study, the overall complication rate after single-session EUS-FNA and ERCP was 10%, and all patients had pancreatitis. According to the previous reports, post-procedural complications occur in 4.0-15.9% of patients undergoing ERCP alone. Pancreatitis reportedly arises in 1.3-7.6% of cases undergoing ERCP alone [11,12,13,14]. Therefore, the overall complication rate of 10% in our study is in concordance with those of previous reports. On the other hand, previous reports revealed that complications occur in 2.0 to 5.0% of patients who underwent EUS-FNA alone. Among them, post-procedure pancreatitis accounts for 0.3-2.0%[15,16,17,18]. Therefore, we consider that carrying out EUS-FNA and ERCP in a single session is as safe as performing each procedure separately. The advantage of this combination procedure is the opportunity to reduce the total time of examination and quickly initiate therapy.

We investigated possible risk factors of post-procedural complications, and we found that only female gender increased the risk. Other patient characteristics and procedural details, such as the mean number of needle passes and procedure time, were not significant risk factors. A previous meta-analysis found that female gender is a risk factor of post-ERCP complications[19].

In our study, the total procedure time of single-session EUS-FNA and ERCP was 61.0 ± 15.8 minutes (range: 27-97 minutes). Mertz and Gautam reported that average time of EUS-FNA alone for pancreatic lesion was 65 minutes[20]. On the other hand, the procedural time of therapeutic ERCP was reportedly 25-50 minutes[21,22]. Moreover, the mean time for the combined procedure described by other researchers ranged from 58.6 to 79.0 minutes[5,8]. Consequently, the total procedure time of 61.0 minutes in our study seemed acceptable.

In our study, the sensitivity of cytodiagnosis by ERCP was significantly lower than that of ESU-FNA. This result is in concordance with previous reports[1,8,23]. In addition, the sensitivity of combined EUS-FNA and ERCP was not statistically higher than that of EUS-FNA alone. Further study regarding the diagnostic accuracy according to the location of the pancreatic mass revealed that, in the subgroup with a pancreatic head mass, cytodiagnosis by ERCP detected cancers in 3 patients that were misdiagnosed by EUS-FNA as benign lesions. On the other hand, in the subgroup of pancreatic body and tail mass, cytodiagnosis by ERCP did not improve the diagnosis. These results indicate that cytodiagnosis by ERCP may play a complementary role in the diagnosis of pancreatic head masses. Otherwise, EUS-FNA should be considered the principal procedure for taking tissue samples from pancreatic masses, as it offers better diagnostic accuracy.

In conclusion, the combined procedure of EUS-FNA and ERCP in a single session appears to be feasible and safe. We believe this combined procedure expedites patient evaluation, eliminates the need for a second endoscopy session, and finally reduces the time required for diagnosis. EUS-FNA should be considered the principal procedure for cytodiagnosis, whereas cytodiagnosis by ERCP has a complementary role in patients with a pancreatic head mass.

Conflict of Interests

The authors report no financial or other conflict of interest relevant to the subject of this article.

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Table 1. Patient characteristics

No. patients	100
Age (years), mean ± SD (range)	64.4±13.6 (24-87)
Gender (male/female)	61/39
Tumor size(mm), mean ± SD (range)	25.6±12.0 (7-68)
Tumor location (head/body/tail)	48/38/14

Table 2. Final diagnosis

	No. of cases
Pancreatic adenocarcinoma	74
Neuroendocrine tumor	9
Chronic pancreatitis	5
Autoimmune pancreatitis	4
Serous cyst adenoma	3
Gastrointestinal stromal tumor	1
Cholangiocarcinoma	1
Metastatic pancreatic tumor	1
Intraductal papillary mucinous carcinoma	1
Pancreatic lipoma	1

Table 3. Risk factors for post-procedural complications

Variable	P value	Odds ratio	(95% C.I.)
Characteristics			
Age>76	0.87	0.88	(0.17-4.45)
Female gender	0.034	4.23	(1.02-17.49)*
Mass location in pancreatic head	0.23	0.43	(0.10-1.76)
Maximum diameter of mass<20mm	0.64	1.41	(0.33-5.93)
Procedual			
No of FNA pass>3	0.13	0.22	(0.026-1.84)
Procedure time of FNA>30min	0.68	1.30	(0.35-4.84)
Difficult cannulation	0.29	2.31	(0.46-11.56)
Precut cannulation	0.14	3.5	(0.60-20.28)
Brush cytology of pancreatic duct	0.79	0.83	(0.22-3.16)
Biliary stent placement	0.40	1.84	(0.43-7.86)
Biliary sphincterotomy	0.29	2.14	(0.50-9.24)
Intraductal ultrasonography	0.76	1.24	(0.29-5.23)
Procedure time or ERCP>30min	0.84	0.87	(0.23-3.3)
Total procedure time>70min	0.70	1.32	(0.31-5.57)

*p<0.05

Table 4. Comparison of diagnostic accuracy between each method

Method	Accuracy, %		Sensitivity, %		Specificity ,%	
EUS-FNA	91.0*	(91/100)	88.2*	(67/76)	100	(67/67)
ERCP	66.0	(66/100)	55.3	(42/76)	100	(24/24)
Combined	94.0†	(94/100)	92.1†	(70/76)	100	(24/24)

combined: combination of EUS-FNA and ERCP.

*$p<0.01$, EUS-FNA vs ERCP. †$p<0.01$, combined vs ERCP.

Table 5. Comparison of diagnostic accuracy according to the tumor location

Method	Accuracy, %		Sensitivity, %		Specificity ,%	
A. Pancreas head (n=48)						
EUS-FNA	87.5*	(42/48)	82.4†	(28/34)	100	(14/14)
ERCP	66.7	(32/48)	52.9	(18/34)	100	(14/14)
Combined	93.8§	(45/48)	91.2§	(31/34)	100	(14/14)
B. Pancreas body and tail (n=52)						
EUS-FNA	94.2†	(49/52)	92.9†	(39/42)	100	(10/10)
ERCP	65.4	(34/52)	57.1	(24/42)	100	(10/10)
Combined	94.2§	(49/52)	92.9§	(39/39)	100	(10/10)

*P<0.05, EUS-FNA vs ERCP. †P<0.01, EUS-FNA vs ERCP.

‡P<0.05, combined vs ERCP. §P<0.01, combined vs ERCP.