의학석사 학위논문

Comparison of Diagnostic Efficacy and Safety between 22-gauge Aspiration and Biopsy Needles for EUS-guided Sampling of Pancreatic Solid Lesions

췌장 고형병변의 진단을 위한 내시경 초음파 유도하 세침흡인술 및 생검술용 22게이지 바늘의 진단능력과 안전성 비교

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Comparison of Diagnostic Efficacy and Safety between 22-gauge Aspiration and Biopsy Needles for EUS-guided Sampling of Pancreatic Solid Lesions

by
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A thesis submitted to the Department of Clinical Meidcal Sciences in partial fulfillment of the requirements for the Degree of Master of Science in Clinical Medical Sciences at Seoul National University College of Medicine

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논문제목 : Comparison of Diagnostic Efficacy and Safety between 22-gauge Aspiration and Biopsy Needles for EUS-guided Sampling of Pancreatic Solid Lesions

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Abstract

Introduction: The advantage of EUS-guided fine needle biopsy (EUS-FNB) over fine needle aspiration (EUS-FNA) is that it allows the acquisition of histologic core tissues. We conducted this study to compare diagnostic efficacy and safety of the new 22-gauge core biopsy needle to those of FNA needle for diagnosis of pancreatic solid lesions in the absence of on-site cytopathologists.

Methods: The Patients who underwent EUS-FNA or FNB between September 2011 and December 2012 were reviewed retrospectively. Among them we enrolled patients who underwent the procedure for diagnosis of pancreatic solid lesion using 22-gauge needle. Diagnostic efficacy and safety were compared between FNA and FNB group. In addition, we analyzed whether the diagnostic yields of EUS-FNA and FNB vary according to the final diagnosis.

Results: A total of 148 patients were enrolled (73 FNA and 75 FNB). Two groups showed comparable diagnosis achievement rates (75.3 vs 84.0%, *P*=0.19), and no severe complication occurred. There were 128 pancreatic cancer (86.5%), 12 neuroendocrine tumor (8.1%), 4 autoimmune pancreatitis (2.7%), and 3 idiopathic pancreatitis (2.0%). In pancreatic cancer patients 68

FNA and 60 FNB were performed. Sensitivities of FNA and FNB were 75.0% and 85.0%, and there was no statistically significant difference (*P*=0.19). The sensitivity of EUS-FNA was similar to that of EUS-FNB in transduodenal puncture (73.9 vs 70.6%, *P*=1.0). In contrast, the sensitivity of EUS-FNA tended to be lower than that of EUS-FNB in transgastric puncture (75.6 vs 90.7%, *P*=0.06). Specificities were 100% in both groups. A total of 12 neuroendocrine tumor (NET) patients were included (3 FNA and 9 FNB). All patients were diagnosed as NET except a patient in the FNB group. Ki-67 index was measured in 5 patients of the FNB group, and it provided crucial information for the management of patients. FNB was performed for 3 autoimmune pancreatitis (AIP) patients, and it enabled histologic diagnosis of AIP for one of them.

Conclusions: In the absence of on-site cytopathologists, EUS-FNB is comparable to FNA for the diagnosis of pancreatic cancer, however FNB might be preferred to FNA when transgastric puncture is performed. EUS-FNB can be helpful in the diagnosis and management of NET and AIP.

Keywords: Endoscopic Ultrasound-Guided Fine Needle Aspiration, Biopsy, Pancreas

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CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

EUS-FNA: Endoscopic ultrasonography-guided fine needle aspiration

EUS-FNB: Endoscopic ultrasonography-guided fine needle biopsy

FNA: Fine needle aspiration

FNB: Fine needle biopsy

EUS: Endoscopic ultrasound

NET: Neuroendocrine tumor

AIP: Autoimmune pancreatitis

IgG: Immunoglobulin G

SD: Standard deviation

Introduction

Endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) has been widely used in the diagnosis of patients with pancreatic disorders, especially solid lesions (Figure 1). A recent meta-analysis reported EUS-FNA had a pooled sensitivity of 86.6% and specificity of 95.8% in diagnosing pancreatic mass (1). Although EUS-FNA is a good diagnostic tool, it has some limitations. The diagnostic accuracy is influenced by the presence of experienced cytopathologists to render on-site diagnosis and accurate cytological analysis (2, 3). In addition, some neoplasms such as lymphoma may be difficult to diagnose without histologic specimen because their tissue architecture and morphology are important for accurate pathologic assessment (4).

In order to get histologic specimen, a EUS-guided fine needle biopsy (EUS-FNB) device (Echotip Procore; Wilson Cook Medical Inc., Winston-Salem, North Carolina, USA) was developed (Figure 2). In a recent randomized trial, diagnostic sufficiency, technical performance, and safety profiles of the 22-gauge biopsy needle were comparable to those of the conventional 22-gauge aspiration needle for sampling of pancreatic mass, most of which were pancreatic cancer (82.1%). In this study on-site cytopathologic evaluation was available (5). On-site analysis is an important factor determining diagnostic efficacy of EUS-FNA (6). However there are still many centers in which on-site cytopathologists are unavailable because of costs and lack of resources.

We performed this study to compare diagnostic efficacy and safety profile of the 22-gauge FNB needle to those of the FNA needle in the absence of on-site cytopathologists. In addition, we investigated whether these parameters are still comparable between both needles irrespective of the final diagnosis.

Materials and Methods

Patients

We reviewed database of consecutive patients who underwent EUS-FNA or FNB for diagnosis of pancreatic solid lesion at Seoul National University Hospital between September 2011 and December 2012. To reduce the heterogeneity according to needle size, only patients who underwent procedures using 22 gauge needles were analyzed. Exclusion criteria were as following: (1) patients who had cystic or mainly cystic masses; (2) patients who underwent core biopsy using Trucut needle (Wilson Cook Medical Inc.). The clinical characteristics of enrolled patients were analyzed. In addition, mass size, location, the type of used needle, and needle pass number were also reviewed. The study was approved by the institutional review board of Seoul National University Hospital.

EUS-FNA and FNB technique

EUS-guided sampling was done by two experienced endoscopists. Procedure was carried out using linear array echoendoscope (GF-UM-2000 or GF-UCT 240; Olympus, Tokyo, Japan) with either the FNA (EchoTip Ultra; Wilson Cook Medical Inc.) or FNB needle (EchoTip Procore; Wilson Cook Medical Inc.).

EUS-FNA was performed as follows; after proper targeting to a mass, the FNA needle was passed through the biopsy channel, and advanced into the

target lesion under EUS guidance, then 10 to 20 times to-and-fro movements were performed with suction using 10-mL syringe. After retracting the needle, the aspirated contents were expressed onto glass slides with the stylet, smeared, and fixed in 99% ethanol.

EUS-FNB was done in the following manner; after proper targeting to a mass, the FNB needle was passed through the biopsy channel, and advanced into the target lesion under EUS guidance. Once the lesion was penetrated, the needle was moved within the lesion several times with stylet withdrawal. Then the acquired tissues were recovered in formalin by pushing the stylet through the needle. The remaining aspirated contents were expressed onto glass slides, smeared, and fixed in 99% ethanol.

While transduodenal passes were done for pancreatic head or uncinate masses, body or tail masses were punctured through the stomach. Because of the absence of on-site cytopathologists, endosonographers assessed the gross adequacy of sample, and selected the number of needle passes.

Outcome measures

The final diagnosis was made based on (1) histologic diagnosis of surgical specimen or (2) clinical follow-up with serial radiologic image.

The results of cytology were reported as following: (1) positive for malignant cells; (2) suspicious for malignant cells; (3) atypical cells; (4) benign cells; (5) inadequate for diagnosis; (6) others (for example, suspicious for neuroendocrine neoplasm). The result was interpreted as malignancy, if it was

positive or suspicious for malignant cells. The results of pathologic examination were reported as following: (1) adenocarcinoma; (2) suspicious for adenocarcinoma; (3) atypical cells; (4) benign cells; (5) inadequate for diagnosis; (6) others (for example, neuroendocrine tumor). If the result was adenocarcinoma or suspicious for adenocarcinoma, it was considered as malignancy. Atypical cells, benign cells, and inadequate for diagnosis were considered as benign disease in both cytologic and pathologic results.

The diagnosis achievement rates were compared between the FNA and FNB groups. Technical failure and severe complication rates were also compared between two groups. Severe complication was defined as life threatening complication such as bleeding, perforation, pancreatitis, and infection. In addition, we analyzed whether the diagnostic yields of EUS-FNA and FNB show differences according to the final diagnosis.

Data Analysis

Student`s *t*-test was used to compare numerical data, and chi-square or Fisher`s exact test was done for comparison of categorical data. Statistical significance was taken as $P<0.05$. All statistical analysis was carried out using SPSS v.17.0 (IBM Corp., Armonk, New York, USA).

Results

A total of 148 patients were enrolled. EUS-FNA was performed for 73 patients (49.3%), and 75 patients underwent EUS-FNB (50.7%). The clinical and technical characteristics are shown in Table 1. There was no significant difference between two groups in age, sex, needle puncture route, needle pass number, and mass size. Overall diagnosis achievement rate was comparable between FNA and FNB groups (75.3 vs 84.0%, respectively, *P*=0.19). Technical failure did not happen in both groups; Needle insertion, puncture, and stylet removal were possible for all cases. There were no severe complications. Final diagnosis was as follows; 128 pancreatic cancer: 86.5%, 12 neuroendocrine tumor (NET): 8.1%, 4 autoimmune pancreatitis (AIP): 2.7%, 3 idiopathic pancreatitis: 2.0%. The remaining one case was pancreatic metastasis from thigh leiomyosarcoma.

Pancreatic cancer

Among 128 pancreatic cancer patients, 68 patients underwent EUS-FNA, and EUS-FNB was performed for 60 patients. The overall sensitivities of EUS-FNA and FNB were 75.0% and 85.0% for pancreatic cancer cases, and there was no statistically significant difference (*P*=0.19). Specificities were 100% for both groups.

Transduodenal puncture was done for 40 pancreatic cancer patients. The sensitivity of EUS-FNA (73.9%) was similar to that of FNB (70.6%) in

transduodenal puncture cases. In contrast, the sensitivity of EUS-FNB (90.7%) tended to be higher than that of FNA (75.6%) in 88 pancreatic cancer patients who underwent transgastric puncture (P=0.06), as shown in Table 2. In pancreatic cancer patients who underwent EUS-FNB, the proportion of successful diagnosis at histologic examination tended to be higher in transgastric puncture compared to transduodenal puncture (74.4% vs 58.5%), albeit it was not statistically significant different (Table 3).

NET

A total of 12 NET patients were included in this study. EUS-FNA was performed for three of them, and cytologic examination revealed cells with neuroendocrine features, which suggested NET. Surgical resection was done for two of them, and NET was confirmed. The other patient showed multiple hypervascular hepatic metastases and serum chromogranin A level elevation, which were compatible with NET. The patient received octreotide and everolimus, and showed partial remission.

EUS-FNB was done for the remaining 9 NET patients. Adequate specimen was acquired in eight of them, and the pathologic findings were all compatible with NET. Immunohistochemical staining was done for six of them, and the results were positive for chromogranin or synaptophysin in all of six patients. EUS-FNB sample was inadequate for a patient. The patient was finally diagnosed as NET by biopsy of hepatic metastasis.

AIP

For three AIP patients, a patient underwent EUS-FNA, and EUS-FNB was done for the other three patients. EUS-FNA revealed only few atypical epithelial cells, and gave no more clues to AIP diagnosis. The level of serum IgG4 increased, and the pancreatic mass disappeared after steroid treatment, so the patient was confirmed as AIP.

Among the three patients who underwent EUS-FNB, only one patient could get histologic clue to diagnosis. The patient complained abdominal pain, and pancreatic NET was suspected at imaging study. EUS-FNB was done, and the pathologic examination revealed lymphoid aggregate and fibrosis. Immunohistochemical staining was positive for IgG and IgG4. The patient received steroid treatment, and showed complete response. In the other two patients, EUS-FNB did not give any clue to AIP diagnosis. One of the two patients showed atrophic glands and fibrosis, and AIP was not suspected in biopsy. The patient underwent surgical resection, because pancreatic cancer was strongly suspected at the imaging study, but the patient was diagnosed as AIP. The other patient presented with jaundice. The imaging study revealed a pancreatic head mass with common bile duct dilation. Upstream pancreatic duct dilation did not exist, and there was another mass at pancreatic tail, which were not typical for pancreatic cancer. EUS-FNB was done, and pathologic findings were focal fibrosis and minimal inflammatory cell infiltration. Immunohistochemical staining was negative for IgG and IgG4. Since AIP could not be excluded, the patient received steroid treatment first,

and showed complete response.

Pancreatic metastasis

A pancreatic metastasis case was included in this study. A 37-year old male presented with a thigh mass, and a pancreatic mass was found incidentally. EUS-FNB was done for pancreatic mass, and malignant mesenchymal tumor was suspected at pathologic examination. Immunohistochemical staining was positive for vimentin and negative for cytokeratin, which was consistent with sarcoma. He received thigh mass excision and pancreaticoduodenectomy, and the final diagnosis was metastatic tumor from thigh leiomyosarcoma.

Discussion

This study showed that the diagnostic yield and safety of the new 22-gauge FNB needle are comparable to those of the 22-gauge FNA needle for sampling of pancreatic mass, however the sensitivity of EUS-FNB tended to be higher than that of FNA for pancreatic cancer when transgastric puncture was attempted.

There are some studies comparing EUS-FNA and FNB using 22-gauge needles, and the results are inconsistent. Bang et al showed that there was no significant difference in diagnostic yield between the 22-gauge aspiration and biopsy needle for EUS-guided sampling of pancreatic mass. In the study the diagnosis achievement rates of FNA and FNB were 100% and 89.3%, respectively (5). Although direct comparison is difficult, the diagnosis achievement rate of FNA seems to be higher than that of our study (75.3%). The presence of on-site cytopathologic analysis may be one of the important factors that caused the high diagnostic efficacy of FNA in this study. In a later prospective comparison study, the correct diagnosis rate of FNA was lower than that of FNB in the pancreatic mass group (75.0 vs. 86.8%, P=0.046). On-site cytopathologic analysis was not performed in this study, and the diagnostic efficacy of FNA is similar to ours. It seems that EUS-FNB is superior to FNA in the absence of on-site cytopathologists, however pancreatic adenocarcinoma cases were only half the patients, and chronic pancreatitis and NET accounted for a relatively large proportion (20.3% and

13.0%, respectively), and comparison of both needles was not specified according to the final diagnosis in this study (7).

Severe complication did not happen in both EUS-FNA and FNB groups. The complication rates of EUS-FNA for pancreatic mass were reported to be 0-2% in a recent review article (8). Although as many studies as EUS-FNA was not carried out, EUS-FNB is also considered as a safe procedure. In a recent feasibility study of the 22-gauge FNB needle, 61 patients underwent EUS-FNB for diagnosis of pancreatic mass, and no complication was reported (9). In the randomized controlled study comparing FNA and FNB needle, only a patient (3.6%) in the FNB group developed mild acute pancreatitis (5).

Our study showed that the sensitivities of EUS-FNA and FNB were comparable for diagnosis of pancreatic cancer (75.0 vs 85.0%, P=0.19), however there was a tendency for the sensitivity of FNB to be higher than that of the FNA in transgastric puncture group (75.6 vs 90.7%, P=0.06). In addition, the sensitivity of FNB had a tendency to be lower in transduodenal puncture (70.6%), and higher in transgastric puncture (90.7%). Originally the 22-gauge FNB needle was developed to overcome the limitation of the 19-gauge needle, which showed technical difficulties when transduodenal passes were done. The needle with a smaller caliber was expected to have advantages in terms of handling and safety (7). However even in the studies using the 22-gauge needle, some failure cases were reported, in which stylet removal from the assembly or needle pass through the working channel was impossible when transduodenal pass was attempted (5, 9). In our study technical failure did not happen, however needle pass from the duodenum was sometimes

difficult, so the needle needed to be pushed out of the scope in the stomach before advancing the scope into the duodenum. This might cause bending of the needle, and impede smooth needle movement, so successful tissue acquisition could be disturbed. The technical difference may be another cause. In EUS-FNB group, tissue acquisition was done with stylet withdrawal. When the echoendoscope is inserted from the stomach to the duodenum, the needle and stylet are more bended. Therefore the withdrawal of stylet is also disturbed, and the negative pressure generated by stylet movements can be lower. In EUS-FNA group, syringe was used to generate suction, and it is less influenced by the location of the tip of echoendoscopes. EUS-FNB has advantage of acquiring histologic core tissues for the diagnosis of pancreatic cancer in the absence of on-site cytopathologic analysis, but it can be disturbed in transduodenal puncture. Previous studies did not cover the relevance between the sensitivity of EUS-FNB and the location of pancreatic cancer (5, 7, 9), so further studies are needed for the conclusive result.

Both EUS-FNA and FNB were performed for NET. Since the number of cases was relatively small, it was difficult to judge which method is better for the diagnosis of NET. The sensitivities of EUS-FNA ranged from 68 to 87% for diagnosis of pancreatic NET in previous studies (10-12). Pais et al reported that the sensitivity of EUS-FNA was 87% for 68 patients. Immunocytochemistry was performed on the sample in 76% of patients, and it was positive in 90% (11). Because the size of FNA needle was not described, we cannot compare these findings with our results. In our study immunohistochemical staining results were all positive for chromogranin or

synaptophysin when tested.

EUS-FNB can be helpful in not only diagnosis but also management of NET. KI-67 staining is very effective for distinguishing well differentiated NET from neuroendocrine carcinoma. NET can be graded if Ki-67 index can be measured in biopsy sample (13). In our study Ki-67 indices were less than 2% in FNB samples of four patients, so they were considered as grade I NET. All of them were non-functioning tumors, and three of them had small tumors (< 2 cm), so these three patients have been followed-up, and tumor progression has not been observed for more than a year. The other patient underwent surgical resection because of the large tumor size (> 2 cm), and was confirmed as grade I NET. Ki-67 index of another patient was more than 20% in biopsy sample. This patient was confirmed as grade III NET after surgical resection.

A previous study reported that EUS-FNA is helpful in the clinical diagnosis of AIP, however it does not provide satisfactory samples for the histologic diagnosis (14). On the other hand EUS-Trucut biopsy was an adequate procedure for obtaining a histological diagnosis in suspected AIP (15). However Trucut needle is stiff; so it is hard to handle (16, 17). To the best of our knowledge, no article was published on the yield of EUS-FNB using the new needle for AIP diagnosis. A total of 3 AIP patients underwent EUS-FNB in our study, and it gave histologic diagnosis clue for one of them. EUS-FNB can be helpful for diagnosis of some AIP patients, but further studies are needed.

There are some limitations of our study. First, this is a retrospective study, and

selection bias may be introduced. Secondly, most cases were pancreatic cancer, so the comparison of EUS-FNA and FNB was difficult in NET and AIP cases. Since NET and AIP are relatively uncommon, multicenter study is needed to compare the diagnostic yields of EUS-FNA and FNB for these cases.

In conclusion, without on-site cytopathologic evaluation, the diagnostic yield and safety of the EUS-FNB using the new 22-gauge needle were comparable to those of FNA for pancreatic cancer. However there was a tendency for the sensitivity of FNB to be higher than that of the FNA, especially in transgastric puncture. EUS-FNB might be preferred to FNA when pancreatic cancer is suspected at body or tail, although further studies are needed. Since the FNA needle costs less than the FNB needle in Korea, EUS-FNA can be selected as the preferential method for sampling when pancreatic head or uncinate cancer is suspected. EUS-FNB can be helpful in the diagnosis and management of NET and AIP.

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TABLES

Table 1 Clinical and technical variables of FNA and FNB groups

	FNA N=73 (49.3%)	**FNB** N=75 (50.7%)	***P value***
Age (mean ± SD, years)	62.0 ± 10.9	61.4 ± 11.5	0.77
Sex (male : female)	41 : 32	39 : 36	0.61
Needle puncture route			0.64
Transgastric	49 (67.1%)	53 (70.7%)	
Transduodenal	24 (32.9%)	22 (29.3%)	
Needle pass number (mean ± SD)	3.5 ± 1.4	3.7 ± 1.4	0.47
Lesion size (mean ± SD, cm)	3.4 ± 0.9	3.2 ± 1.1	0.13
Diagnosis achievement	55 (75.3%)	63 (84.0%)	0.19

Table 2 Sensitivity and specificity of FNA and FNB groups (pancreatic cancer)

	FNA N=68 (56.7%)	**FNB** N=60 (43.3%)	***P value***
Sensitivity	75.0%	85.0%	0.19
Specificity	100%	100%	1.00
Transduodenal puncture (N)	23	17	
sensitivity	73.9%	70.6%	1.00
Transgastric puncture (N)	45	43	
sensitivity	75.6%	90.7%	0.06

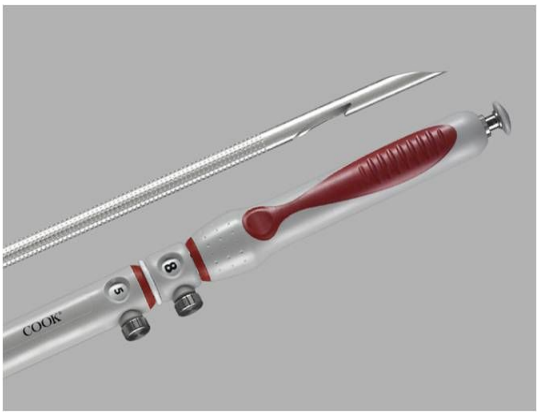
Table 3 Successful diagnosis at histologic examination

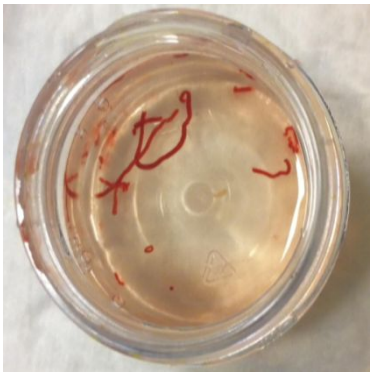
	Transgastric puncture N=43	**Transduodenal puncture** N=17	***P value***
Successful, N (%)	32 (74.4%)	10 (58.8%)	0.24
Unsuccessful, N (%)	11 (25.6%)	7 (41.2%)	

FIGURES

Figure 1　EUS-FNA device and specimen

Figure 2　EUS-FNB device and specimen





국문 초록

췌장 고형병변의 진단을 위한 내시경 초음파 유도하 세침흡인술 및 생검술용 22 게이지 바늘의 진단능력과 안전성 비교

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서론: 내시경 초음파 유도하 생검술은 세침흡인술에 비해 조직병리학적 검사가 가능한 검체를 얻을 수 있다는 장점이 있다. 본 연구에서는 현장 병리의사가 없는 상황에서 췌장 고형병변의 진단에 있어 내시경 초음파 유도하 세침흡인술 및 생검술용 22 게이지 바늘의 진단능력과 안전성을 비교하고자 하였다.

방법: 서울대학교 병원에서 2011 년 9 월부터 2012 년 12 월에 걸쳐 췌장 고형병변의 진단을 위해 22 게이지 바늘을 이용, 내시경 초음파 유도하 세침흡인술 혹은 생검술을 시행받은 148 명의 환자를 후향적으로 분석하였다. 세침흡인술을 받은 환자군과 생검술을

받은 환자군 사이에 각 검사법의 진단능력과 안전성을 비교하였고, 추가적으로 최종 진단의 종류에 따라 각 검사법의 진단능력이 변화하는지를 분석하였다.

결과: 세침흡인술을 시행받은 73명, 생검술을 시행받은 75 명의 환자에서 각 검사의 진단률은 통계학적인 차이를 보이지 않았고 (75.3% vs 84.0%, *P*=0.19) 심각한 부작용은 두 군 모두에서 발생하지 않았다. 최종 진단을 살펴보면 췌장암 128 명 (86.5%), 신경내분비종양 12 명 (8.1%), 자가면역성 췌장염 4 명 (2.7%), 특발성 췌장염 3 명 (2.0%)이 포함되었다. 췌장암 환자군에서는 68 명이 세침흡인술, 60 명이 생검술을 시행받았고 두 검사법의 민감도 사이에 통계학적인 차이는 없었다 (75.0% vs 85.0%, *P*=0.19). 췌장암 환자군에서 십이지장을 통해 바늘을 천자한 경우 세침흡인술과 생검술 사이에 민감도의 차이는 없었다 (73.9% vs 70.6%, *P*=1.0). 위를 통해 바늘을 천자한 경우 생검술의 민감도 (90.7%)가 세침흡인술 (75.6%) 에 비해 높은 경향을 보였다 (*P*=0.06). 특이도는 두 검사법 모두에서 100% 로 나타났다. 신경내분비종양 환자군에서는 3 명이 세침흡인술, 9 명이 생검술을 시행받았고 생검술을 시행받은 1 명을 제외하고 모든 환자에서 진단이 가능하였다. Ki-67 index 는 생검술을 시행받은 환자중 5 명에서 측정되었고 이를 통해 치료 방침 결정에 중요한 정보를 얻을 수 있었다. 자가면역성 췌장염 환자군에서는 3 명이 생검술을 시행받았고 이 가운데

1 명에서 병리학적 진단이 가능하였다.

결론: 현장 병리의사가 없는 상황에서 췌장암의 진단에 있어 내시경 초음파 유도하 생검술은 안전하며 세침흡인술과 유사한 진단능력을 보이지만, 위를 통해 바늘을 천자하는 경우 생검술을 먼저 시행해 볼 수 있겠다. 내시경 초음파 유도하 생검술은 췌장 신경내분비 종양과 자가면역성 췌장염의 진단 및 치료에 도움을 줄 수 있다.

주요어: 내시경 초음파 유도하 세침흡인술, 생검, 췌장

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