대한영상의학회지

Safety and Efficacy of Ultrasound-Guided Percutaneous Core Needle Biopsy of Pancreatic and Peripancreatic Lesions Adjacent to Critical Vessels

주요 혈관 근처의 췌장 또는 췌장 주위 병변에 대한 초음파 유도하 경피적 중심 바늘 생검의 안전성과 효율성

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Purpose To evaluate the safety and efficacy of ultrasound-guided percutaneous core needle biopsy (USPCB) of pancreatic and peripancreatic lesions adjacent to critical vessels.

Materials and Methods Data were collected retrospectively from 162 patients who underwent USPCB of the pancreas ($n = 98$), the peripancreatic area adjacent to the portal vein, the para-aortic area adjacent to pancreatic uncinate ($n = 34$), and lesions on the third duodenal portion ($n = 30$) during a 10-year period. An automated biopsy gun with an 18-gauge needle was used for biopsies under US guidance. The USPCB results were compared with those of the final follow-up imaging performed postoperatively. The diagnostic accuracy and major complication rate of the USPCB were calculated. Multiple factors were evaluated for the prediction of successful biopsies using univariate and multivariate analyses.

Results The histopathologic diagnosis from USPCB was correct in 149 (92%) patients. The major complication rate was 3%. Four cases of mesenteric hematomas and one intramural hematoma of the duodenum occurred during the study period. The following factors were significantly associated with successful biopsies: a transmesenteric biopsy route rather than a transgastric or transenteric route; good visualization of targets; and evaluation of the entire US pathway. In addition, the number of biopsies required was less when the biopsy was successful.

Conclusion USPCB demonstrated high diagnostic accuracy and a low complication rate for the histopathologic diagnosis of pancreatic and peripancreatic lesions adjacent to critical vessels.

Index terms Biopsy; Image-Guided Biopsy; Pancreatic Neoplasms; Ultrasonography; Retroperitoneal Neoplasms

INTRODUCTION

With recent advances in targeted therapies of cancers, the importance of genomic analysis for molecular subtyping is being emphasized and obtaining a sample of tumor tissue is essential for these analyses (1). Ultrasound-guided percutaneous core needle biopsy (USPCB) is an accurate, safe, and widely accepted technique for the tissue diagnosis of various lesions in the abdomen. US-guidance has a number of advantages over other imaging tools for percutaneous biopsy of intra-abdominal lesions, which include real-time visualization of the biopsy needle pathway and targets during the procedure, wide availability, portability, lack of exposure to ionizing radiation, a relatively short procedure time, and a lower cost (2). However, it has been considered difficult to apply USPCB for pancreatic and peripancreatic lesions adjacent to critical vessels due to the overlying bowel loop and solid viscera, and the limited field of view of US-guidance (3, 4). In these cases, laparotomy has been used as an alternative, but it is more invasive, complicated, and expensive, undesirable features of a diagnostic modality (5). Therefore, the objective of this study was to evaluate the safety and efficacy of USPCB for pancreatic and peripancreatic lesion adjacent to portal vein, or paraaortic lesion adjacent to pancreatic uncinate and duodenal 3rd portion.

MATERIALS AND METHODS

PATIENT POPULATION

This retrospective study was approved by our Institutional Review Board, which waived patient informed consent (IRB No. EUMC 2020-04-018-001). Between January 2009 and December 2018, a total of 162 consecutive patients (87 male and 75 female; mean age, 62.8 years) who underwent USPCB of pancreas, peripancreatic lesion adjacent to portal vein, or paraaortic lesion adjacent to pancreatic uncinate and duodenal 3rd portion lesions for pathological confirmation were included. USPCB was selected for patients with an inoperable malignancy or an uncertain diagnosis on imaging. In these patients, a tissue sample was necessary to guide treatment planning. All included patients had an international normalized ratio < 1.5 and a platelet count > 50000 cells/mL.

BIOPSY PROCEDURES

The safest biopsy pathway with the lowest possibility of injuring major organs was selected by using US. High resolution US (iU 22 and Epiq 7; Philips Medical Systems, Bothwell, WA, USA) was used for the examination by applying a 2–5 MHz convex transducer. Two authors (J.K.L., with 9 years of experience with USPCB at the beginning of the study, J.S.K., with 3 years of experience with USPCB) performed all of the biopsy procedures in this study by using a freehand technique with Doppler US. The authors tried to place the needle at the target after passing through the mesentery while avoiding adjacent major vessels or organs during real-time US (Fig. 1). If the pathway of the needle could not avoid the overlying bowel, a transgastric or transenteric route was chosen instead (Fig. 2). An automated biopsy gun (Pro-Mag Automatic Biopsy System; Manan Medical Products, Northbrook, Ill or Acecut; TSK Labs., Tokyo, Japan and Ingenor, Paris, France) with an 18-gauge biopsy needle and a 1 to 2.5-

Fig. 1. A 67-year-old male with a pancreatic mass.
A. Contrast-enhanced CT shows an ill-defined low-density mass in the pancreatic uncinate process (arrow).
B. A transverse US scan clearly visualizes a 1.8-cm mass in the uncinate process.
C. A transverse US scan shows the path of the biopsy needle through the transmesenteric route (arrows). The skin-to-target distance is 4.3 cm.
Pathologic examination of the US-guided percutaneous core needle biopsy specimen revealed a case of pancreatic ductal adenocarcinoma.
US = ultrasound

Fig. 2. A 78-year-old male with a peripancreatic mass adjacent to the portal vein.
A. Contrast-enhanced CT shows a low-density mass in the hepatoduodenal ligament adjacent to the pancreatic head (arrow).
B. A transverse US scan clearly visualizes a 1.3-cm, enlarged lymph node in the hepatoduodenal ligament.
C. A transverse US scan shows the path of the biopsy needle through the transgastric route (arrows). The skin-to-target distance is 5.9 cm.
Pathologic examination of the US-guided percutaneous core needle biopsy specimen revealed a case of metastatic lymphadenopathy from duodenal adenocarcinoma.
US = ultrasound
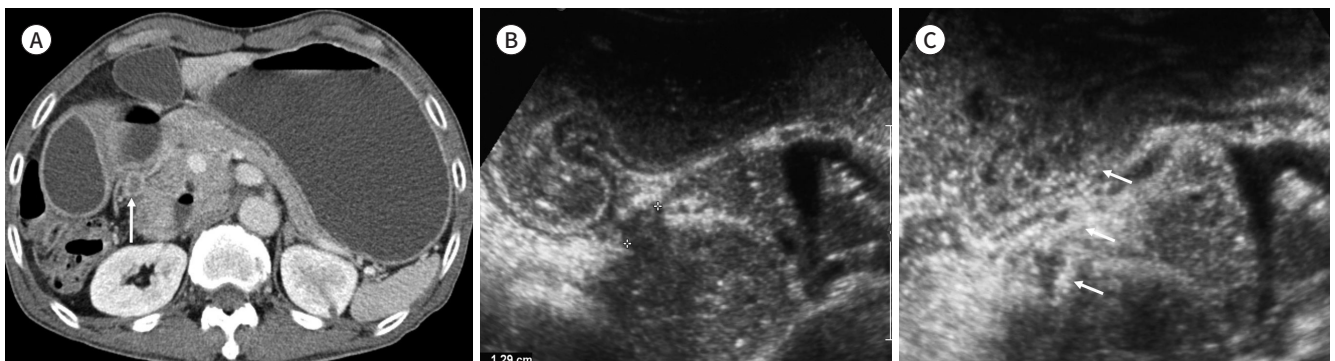
cm cutting groove was used. Patients fasted for at least 6 hours prior to biopsy and were placed in the supine position. Local anesthesia was applied to the skin by administration of 2% lidocaine and conscious sedation was not administered. Immediate biopsy complications, such as hemorrhage, were evaluated with US after the procedures.

EVALUATION OF FACTORS ASSOCIATED WITH SUCCESSFUL BIOPSIES

All patients underwent contrast-enhanced CT for initial diagnosis and follow-up. The size and location of the targets were evaluated on the initial contrast-enhanced CT. The access route, transmesenteric, transgastric or transenteric, was determined by US during the biopsy procedure. The skin-to-target distance was measured by US from the skin to the anterior surface of the target, following the chosen needle pathway. US visualization of the targets and pathway was evaluated subjectively by the operator as good and moderate. The approach was considered good if the boundary of the target and the entire pathway were clearly de-

marcated and not obscured by artifacts from bowel gas or the patients' body habitus. The approach was considered moderate if the target or pathway was not completely demarcated or partly obscured by artifacts. The number of biopsies taken and the occurrence of complications were also evaluated.

REFERENCE STANDARD

The final diagnoses were confirmed with the results of concurrent surgery or follow-up evaluation after the biopsies. Fifteen (12%) patients underwent surgery and the remaining 147 (88%) patients underwent clinical observation and follow-up imaging evaluation. The follow-up intervals ranged between 4 weeks and 120 months for both clinical observation (mean interval, 15 months) and imaging (mean interval, 14 months).

STATISTICAL ANALYSIS

The diagnostic accuracy and major complication rate of USPCB were calculated. Factors associated with successful biopsies were assessed by using logistic regression analysis. The possible factors analyzed were age, sex, the size and location of the biopsy targets, access route, skin-to-target distance, US visualization of targets and the entire pathway, the number of biopsies, and the occurrence of complications. A univariate analysis was used to assess statistical differences in the factors. A multivariate analysis was used to determine the best predictors of successful biopsies. The multivariate analysis was performed with a $p < 0.05$ level of significance as a retention criterion. $p < 0.05$ was considered to indicate statistical significance. All statistical analyses were performed using SPSS version 20.0 for Windows statistical software (IBM Corp., Armonk, NY, USA).

RESULTS

BASELINE CHARACTERISTICS

A summary of the patients' characteristics and their biopsy data is provided in Table 1. Histopathologic diagnosis of the specimens obtained by USPCB was correct in 149 (92%) of 162 patients. Thirteen (8%) of 162 patients were not correctly diagnosed by USPCB due to insufficient specimen material ($n = 3$) or an incorrect diagnosis ($n = 10$). The final diagnoses were primary pancreatic malignancy in 78 patients, metastasis or metastatic lymphadenopathy in 44, lymphoma in seven, tuberculous lymphadenitis in 11, chronic pancreatitis in seven, retroperitoneal sarcoma in three, and other benign tumor/inflammation in 12. The three patients with insufficient specimen material were confirmed to have metastasis in two and lymphoma in one. The incorrect diagnoses of the USPCB specimens included no tumor found in the specimen and chronic inflammation or necrosis, which was finally confirmed as a primary pancreatic malignancy in four patients, metastasis in four, and benign tumor/ inflammation in two (Fig. 3).

ANALYSIS OF FACTORS ASSOCIATED WITH SUCCESSFUL BIOPSIES

Univariate analysis revealed that the transmesenteric biopsy route, good visualization of targets and the pathway, and a lower number of biopsies were statistically significant factors

associated with successful biopsies (Table 2). The size and location of the targets, the skin-to-target distance, and the occurrence of complications did not have a significant correlation with successful biopsies. Multivariate analysis performed with the factors significant in the univariate analysis revealed that the transmesenteric biopsy route, good visualization of targets and the pathway, and a lower number of biopsies were statistically significant factors,

Table 1. Summary of Patient Characteristics and Biopsy Data

Variable	Number	Mean (Range)
Age (years)		62.7 (20–86)
Sex		
Male	87 (53.7)	
Female	75 (46.3)	
Target size (cm)		2.7 (0.8–10.7)
Target location		
Pancreas	98 (60.5)	
Periportal*	34 (21.0)	
Paraaortic†	30 (18.5)	
Length of pathway (cm)		4.3 (1.7–9.5)
Biopsy route		
Transmesenteric	119	
Trans-gastric or -enteric	43	
Ultrasound visualization of target and pathway		
Good	155	
Moderate	7	
Number of biopsies		1.8 (1–5)
Complication	5 (3.1)	

Data in parentheses are percentages.
*Peripancreatic area adjacent to portal vein.
†Paraaortic area adjacent to pancreatic uncinate and duodenal 3rd portion.

Fig. 3. A 69-year-old female with a pancreatic mass adjacent to the aorta.
A. Contrast-enhanced CT shows a low-density mass in the posterior portion of the pancreatic head (arrow).
B. A transverse US scan shows a 1.9 cm mass in the posterior portion of the pancreatic head, and both lateral margins are partly obscured by artifacts.
C. A transverse US scan shows the pathway of the biopsy needle through the transgastric route (arrows). The pathway was not completely demarcated. The skin-to-target distance was 5.7 cm. Pathologic examination found no tumor in the US-guided percutaneous core needle biopsy specimen. Finally, the patient was diagnosed with pancreatic ductal adenocarcinoma.
US = ultrasound

Table 2. Univariate Analysis of Factors Associated with Successful Biopsies

Variables	Odds Ratio	95% Confidence Interval	*p*-Value
Age	0.98	0.94–1.03	0.376
Sex			0.277
Male	0.53	0.16–1.68	
Female	1 (reference)		
Target size	1.38	0.83–2.27	0.215
Target location			0.276
Pancreas	1.88	0.60–5.89	
Periportal or paraaortic*	1 (reference)		
Length of pathway (cm)	0.83	0.59–1.16	0.825
Biopsy route			0.027
Transmesenteric	3.66	1.12–11.60	
Trans-gastric or -enteric	1 (reference)		
Ultrasound visualization of target and pathway			0.004
Good	10.87	2.13–55.41	
Moderate	1 (reference)		
Number of biopsies	0.49	0.27–0.89	0.018
Complication	3.02	0.31–29.21	0.340

*Peripancreatic area adjacent to portal vein, or paraaortic area adjacent to pancreatic uncinate and duodenal 3rd portion.

Table 3. Multivariate Analysis of Factors Associated with Successful Biopsies

Variable	Odds Ratio	95% Confidence Interval	*p*-Value
Biopsy route			0.015
Transmesenteric	5.46	1.39–21.42	
Trans-gastric or -enteric	1 (reference)		
Ultrasound visualization of target and pathway			0.004
Good	19.68	2.61–148.44	
Moderate	1 (reference)		
Number of biopsies	0.46	0.22–0.97	0.041

and good visualization of the targets and the entire pathway was the strongest predictor of a successful biopsy (Table 3).

COMPLICATIONS

Complications occurred in five of 162 patients, a rate of 3.1%. Mesenteric hematoma occurred in four patients, in whom three had biopsy targets located in peripancreatic area adjacent to portal vein and one had a target located in paraaortic area adjacent to duodenal 3rd portion. Three of these four patients had correct diagnoses from the biopsied specimen, which were retroperitoneal fibrosis, tuberculous lymphadenitis, and vasculitis. The other patient, with a peripancreatic target adjacent to portal vein had no tumor in the biopsied specimen but the lesion was finally confirmed as metastatic lymphadenopathy. All four patients had abdominal pain after USPCB, founded that small amount of peri-lesional mesenteric he-

matoma without active bleeding on post procedure CT. But the patients had stable vital signs and recovered completely on follow up CT with conservative treatment. Via transenteric (transduodenal) route, intramural hematoma of the duodenum occurred on CT in one patient with a metastatic mass in the paraaortic area adjacent to duodenal 3rd portion (Fig. 4). This patient was discharged asymptomatic immediately after USPCB, but had abdominal pain 2 weeks later, and an intramural hematoma of duodenum was accidentally found on CT. The patient was treated with percutaneous catheter insertion into the hematoma and follow up CT showed a complete resolution. Peritoneal metastasis or needle tract seeding were not identified during the follow-up period.

Fig. 4. A 78-year-old female with a medical history of ovarian cancer.
**A.** Contrast-enhanced CT shows an enlarged lymph node in the paraaortic area adjacent to the third duodenal portion (arrow).
B. A transverse US scan clearly shows a 1.3-cm mass in the aortocaval space. Note the duodenum anterior to the mass (arrowheads).
C. A transverse US scan clearly shows the path of the biopsy needle through transenteric route (arrows). The skin-to-target distance is 5 cm. Pathologic examination of the USPCB specimen revealed a case of metastatic carcinoma.
D. Contrast-enhanced CT image acquired 2 weeks after the USPCB shows an intramural hematoma of the third duodenal portion (arrows). The patient was treated with percutaneous catheter insertion and has completely recovered.
US = ultrasound, USPCB = US-guided percutaneous core needle biopsy
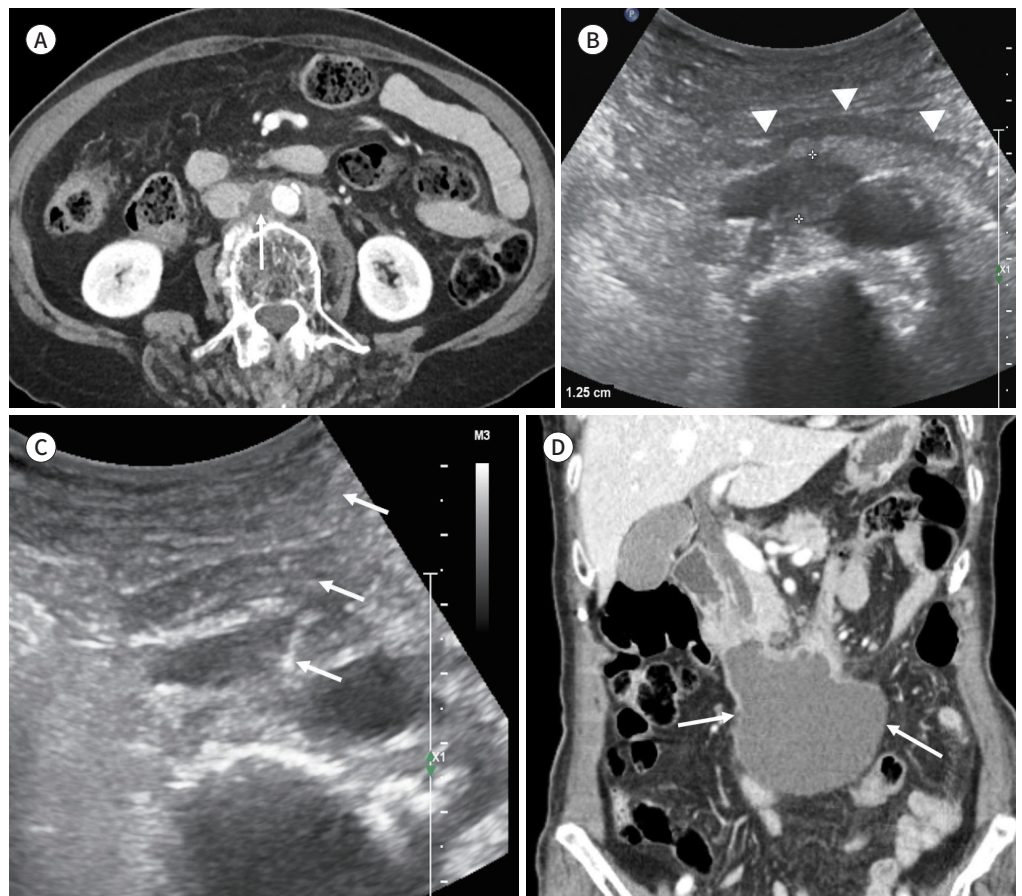
DISCUSSION

In this era of targeted therapy, molecular diagnostics plays an important role in the clinical management of patients with solid organ malignancies. Oncologists are increasingly using genomic analysis to uncover mutations amenable to targeted therapies in advanced cancers, especially those with a poor prognosis and limited treatment options (6-9). Due to tumor heterogeneity, obtaining a complete histologic sample for evaluation of molecular marker expression has become of paramount importance (10). In the case of pancreatic cancer, endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) has been widely used for cytological diagnosis of pancreatic solid neoplasms, and its reported cytological diagnostic accuracy is 89.7%–90% (11, 12). However, the reported histological diagnostic accuracy of EUS-FNA is only 77.6%–80%, because samples from EUS-FNA are not adequate for full histologic diagnosis, including immunohistochemical staining. Endoscopic ultrasound-guided fine needle biopsy (EUS-FNB) with a firing system has become an alternative to acquire adequate histological samples (13-16). However, EUS-FNB has difficulties in transduodenal approaches, and requires a long learning curve to master the technique (11, 17).

In this study, even one tissue core from USPCB using an 18-gauge needle with a 1- to 2.5-cm cutting groove was sufficient for all types of histologic diagnosis regardless of whether the primary lesion was benign or malignant. Furthermore, the process of USPCB was simple, fast, cost-effective, and required no sedation. The entire procedure time was only 10 to 20 minutes. Radiologists with experience with US-guidance and free-hand techniques of taking biopsies of abdominal organs may adjust quickly to USPCB of the pancreas.

Although only a few reports about USPCB of retroperitoneal lesions are available, USPCB has been reported as an effective method for histologic diagnosis of both superficial and deep lymph nodes with diameters as small as 1 cm (2, 18, 19). Tomozawa et al. (4) reported that CT-guided needle biopsy showed a sensitivity of 93%, a specificity of 100%, and an accuracy of 93% for pathologic diagnosis of retroperitoneal lesions. They remarked that the continuous localization of retroperitoneal lesions and sufficient control of the needle tract were difficult due to the smaller field of view on US-guidance than on CT. Unlike these result, our study found 92% diagnostic accuracy using US-guidance, which is similar to the results from a study using CT-guidance. We experienced many advantages of the US-guidance, which included real-time guidance through the entire path of the biopsy needle from the skin to the target in multiple planes, demarcation of adjacent vessels by Doppler US, shortening of the skin-to-target distance and moving the overlying bowels off the targets by compression with the US probe, and besides, there was no radiation hazard and a short procedure time.

In the analysis of factors associated with successful biopsies, good visualization of the targets and needle pathway, and the availability of a transmesenteric route for the needle path were significant factors. Penetration of the stomach or small bowel in a transgastric or transenteric route may spoil the sonic window of the needle pathway and the target. Interestingly, the size of the target and the skin-to-target distance were not significant factors for successful biopsies, which might mean that even a small para-aortic lesion adjacent to pancreatic uncinate and duodenal 3rd portion in an obese patient can be biopsied without difficulty as long as the target lesion and the pathway can be visualized well on US. In cases of the acquisition

of an adequate sample from the first USPCB, additional needle passes would not be necessary. Therefore, fewer number of biopsies may be another factor predicting a successful biopsy, but it has some consequential aspects. In fact, when using USPCB for pancreas or peripancreatic lesions, there are few cases of pricking more than 3 times because the sonic window is poor due to hematoma or mesenteric edema.

This study has some limitations. First, selection bias may exist. We did not perform USPCB on every patient with a deep-seated lesion in the abdomen which is classified as 'poor' US visualization that required a pathologic diagnosis at our hospital. In the clinical practice, many poor US visualized lesions are also performed with EUS-FNA or FNB, a comparison of safety and efficiency between USPCB and EUS-FNA or FNB for poor US visualized lesions is needed. However, at our institute, almost all inoperable pancreatic lesions were biopsied under US-guidance for histologic diagnosis. Second, this study represents the retrospective experience of only a single center, and the results may not translate into similar outcomes at other sites.

In conclusion, our results demonstrated that USPCB is a safe and effective method with a high diagnostic accuracy and a low complication rate for the histopathologic diagnosis of the pancreas and peripancreatic lesion adjacent to portal vein and paraaortic lesion adjacent to pancreatic uncinate and duodenal 3rd portion. Clear visualization of biopsy targets on US-guidance using the transmesenteric pathway, and avoiding transgastric or transenteric routes, are both essential for successful biopsies, which together may also reduce the required number of needle passes.

Author Contributions

Conceptualization, L.J.K.; data curation, all authors; formal analysis, C.S.H., L.J.K.; methodology, L.J.K., C.S.H.; resources, C.S.H., K.H.J., L.H.J.; supervision, L.J.K.; validation, K.J.S., L.J.K.; visualization, L.H.J., K.H.J.; writing—original draft, C.S.H.; and writing—review & editing, C.S.H., L.J.K.

Conflicts of Interest

The authors have no potential conflicts of interest to disclose.

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대한영상의학회지

주요 혈관 근처의 췌장 또는 췌장 주위 병변에 대한 초음파 유도하 경피적 중심 바늘 생검의 안전성과 효율성

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목적 췌장 및 췌장 주위의 주요 혈관에 인접한 병변에 대하여 초음파 유도하 경피적 중심 바늘 생검(ultrasound-guided percutaneous core needle biopsy; 이하 USPCB)의 안전성과 효능을 평가하였다.

대상과 방법 10년 동안 췌장($n = 98$), 간문맥 근처 췌장 주위($n = 34$), 또는 췌장 갈고리돌기 부위와 십이지장 제3부분과 인접한 대동맥주위($n = 30$) 병변에 대하여 USPCB를 시행받은 162명의 환자의 검사 결과를 수집하였다. 초음파 유도하18게이지 바늘을 가진 자동 생검 총을 사용하였고, USPCB 결과는 수술 결과 또는 추적 관찰 영상과 비교하였다. USPCB의 진단 정확도 및 주요 합병증 비율을 계산했으며, 성공적인 생검의 예측을 위한 요인이 무엇인지 단변량 및 다변량 분석을 사용하여 평가하였다.

결과 USPCB에서 조직 병리학 진단은 149명(92%) 환자에서 일치했다. 주요 합병증은 장간막 혈종 4건과 십이지장 벽내혈종 1건이 발생했다(3%). 성공적인 생검을 위한 요인으로는 위 또는 장관을 통과하는 경로보다는 경장간막 경로를 이용할수록, 초음파상 표적 및 생검 경로가 잘 보일수록 등이 포함되었다. 또한 결과적으로 생검에 성공한 경우 생검 횟수가 더 적었다.

결론 USPCB는 주요 혈관에 인접한 췌장 및 간문맥 근처 췌장 주위 병변 또는 췌장 갈고리돌기 부위나 십이지장 제3부분과 인접한 대동맥 주위 병변의 조직학적 진단을 위한 높은 정확도 및 낮은 합병증 비율을 나타냈다.

이화여자대학교 의과대학 부속 이대목동병원 영상의학과