의학석사 학위논문

Safety and diagnostic accuracy of endoscopic ultrasound guided spleen biopsy

내시경초음파 유도하 비장 조직 검사의 유용성 및 안전성

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이 정 환

Safety and diagnostic accuracy of endoscopic ultrasound guided spleen biopsy

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이 논문을 의학석사 학위 논문으로 제출함

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이정환의 의학석사 학위 논문을 인준함

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Abstract

Background and aims: Percutaneous biopsies are used for the diagnosis of spleen lesions. Much lower adverse event rates for percutaneous splenic biopsies have been demonstrated in recent studies compared with the adverse event rates in previous investigations. However, the risk of serious adverse events is still concerning. Endoscopic ultrasound (EUS)-guided biopsy is also an accepted technique for splenic tissue acquisition. However, the two biopsy methods have not been compared. Thus, we compared the clinical outcomes and adverse events of the two techniques.

Methods: This retrospective analysis included 60 patients who underwent EUS-guided or percutaneous spleen biopsies from 2015 to 2021. The clinical outcomes and adverse events were evaluated.

Results: Thirty-six biopsies were EUS-guided and 24 were percutaneous. The sensitivity, specificity, and accuracy were 90.0%, 100%, and 96.8% in the EUS group, and 92.3%, 100%, and 95.0% in the percutaneous group, respectively. Twenty-one diagnoses (35%) were malignant, and the most common diagnosis was lymphoma. Major adverse events occurred in two patients in the percutaneous group, and one of the adverse events required transcatheter arterial embolization and splenectomy due to hemorrhage. No major adverse events were observed in the EUS group, and the overall adverse event rate was significantly lower in the EUS group compared with the rate in the percutaneous group ($p = 0.023$).

Conclusions: EUS-guided spleen biopsies are safe and accurate, with high diagnostic accuracy. The risk of adverse events may be lower for EUS-guided biopsies compared with the rate for percutaneous biopsies.

Key words: Endoscopic ultrasound-guided biopsy, percutaneous biopsy, spleen

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Introduction

The spleen participates in hematologic and immunologic homeostasis.[1] Although the spleen is not commonly affected by diseases, malignant and infectious diseases may occur.[2,3] Diseases involving the spleen are often difficult to diagnose using only serologic and imaging tests. Therefore, tissue samples from the spleen are often required for a definitive diagnosis.[4,5] Traditionally, methods of acquiring splenic tissue have included splenectomy and percutaneous biopsies.[6,7] As splenectomy is invasive and involves relatively high morbidity (8.6%–37%) and mortality (0%–2.9%) rates, percutaneous biopsy has been used as an alternative method.[2,6,8] However, percutaneous biopsy procedures have not been widely performed due to concerns of hemorrhage after the procedure. This reluctance may be related to an early report demonstrating a high major adverse event rate for percutaneous biopsies of the spleen performed with a core needle.[9] More recent studies of percutaneous splenic biopsies using smaller needle diameters have shown relatively low overall adverse event rates and high diagnostic yields.[2,10,11] However, some concerns about the risk of serious adverse events after percutaneous biopsy of the spleen remain, especially regarding major hemorrhagic complications requiring transcatheter arterial embolization or urgent splenectomies.[10,12]

Endoscopic ultrasound (EUS)-guided spleen biopsy is the newest method of splenic tissue acquisition.[13,14] EUS-guided biopsies are safe and effective for acquiring tissue samples from intra-abdominal organs using a curved linear-array echoendoscope with various needles.[15,16] The whole spleen can be observed through the gastric wall using EUS, and the biopsy needle is inserted endoscopically via the transgastric route.[17] EUS is a novel approach to sampling a splenic mass; the core biopsy needle traverses less tissue and may reduce the risk of hemorrhage.[13] Both percutaneous biopsies and EUS biopsies are performed in the spleen. However, no studies compared these two biopsy methods. Therefore, we compared the clinical outcomes and adverse events for percutaneous and EUS spleen biopsies.

Materials and Methods

Patients

This study was approved by the Asan Medical Center, Institutional Review Board, and the requirement for informed consent was waived. The retrospective study included 60 patients who underwent spleen biopsies from 2015 to 2021. The cases were classified into two groups for comparison: an EUS biopsy group and a percutaneous biopsy group.

Procedures

EUS-guided procedures were performed under sedation by gastroenterologists who perform more than 500 EUS procedures annually. A linear-array echoendoscope (GF-UCT260, Olympus Medical Systems) was used for EUS-guided biopsies. The spleen was punctured through a transgastric approach (Figure 1). The puncture needle was 19–22 G and was selected at the operator's discretion. Color Doppler was used to evaluate blood flow in the needle path to avoid puncturing major blood vessels. Patients were monitored for at least 12–24 hours after the procedure with regular vital checks.

The percutaneous biopsy procedures were performed by radiologists (Figure 1). Patients were placed in the supine or right decubitus position to best visualize the spleen with the shortest approach (either subcostal or intercostal). Procedures were performed under local anesthesia and analgesics. An 18-G needle was typically used for percutaneous biopsies. A post-procedure scan was performed to ensure that there was no internal bleeding. Ultrasound-guided probe compression or manual compression was applied for 5–10 minutes after the biopsy. Patients were monitored for at least 12–24 hours after the procedure with regular vital checks.

Data collection

Platelet counts, prothrombin time, international normalized ratio, and activated partial thromboplastin time were assessed to evaluate hemostatic function. Platelet counts of more than 50x103/UL, a prothrombin activity of more than 50% of the normal control, and normal partial thromboplastin time were required for needle biopsies. Platelets were transfused in one patient with a platelet count of $24x10^3$/UL.

Patients' clinical information and final pathology reports were reviewed to determine the diagnostic accuracy of the biopsy. The results of the splenic biopsies were compared with pathological reference standards (splenectomy or tissue obtained from another anatomic site) or longitudinal clinical or imaging follow-up for a minimum of 1 year. Sensitivity, specificity, accuracy, positive predictive value (PPV), and negative predictive value (NPV) were calculated using subsequent clinical and imaging follow-up data. The biopsy results were considered nondiagnostic if the specimen was inadequate for diagnostic purposes.

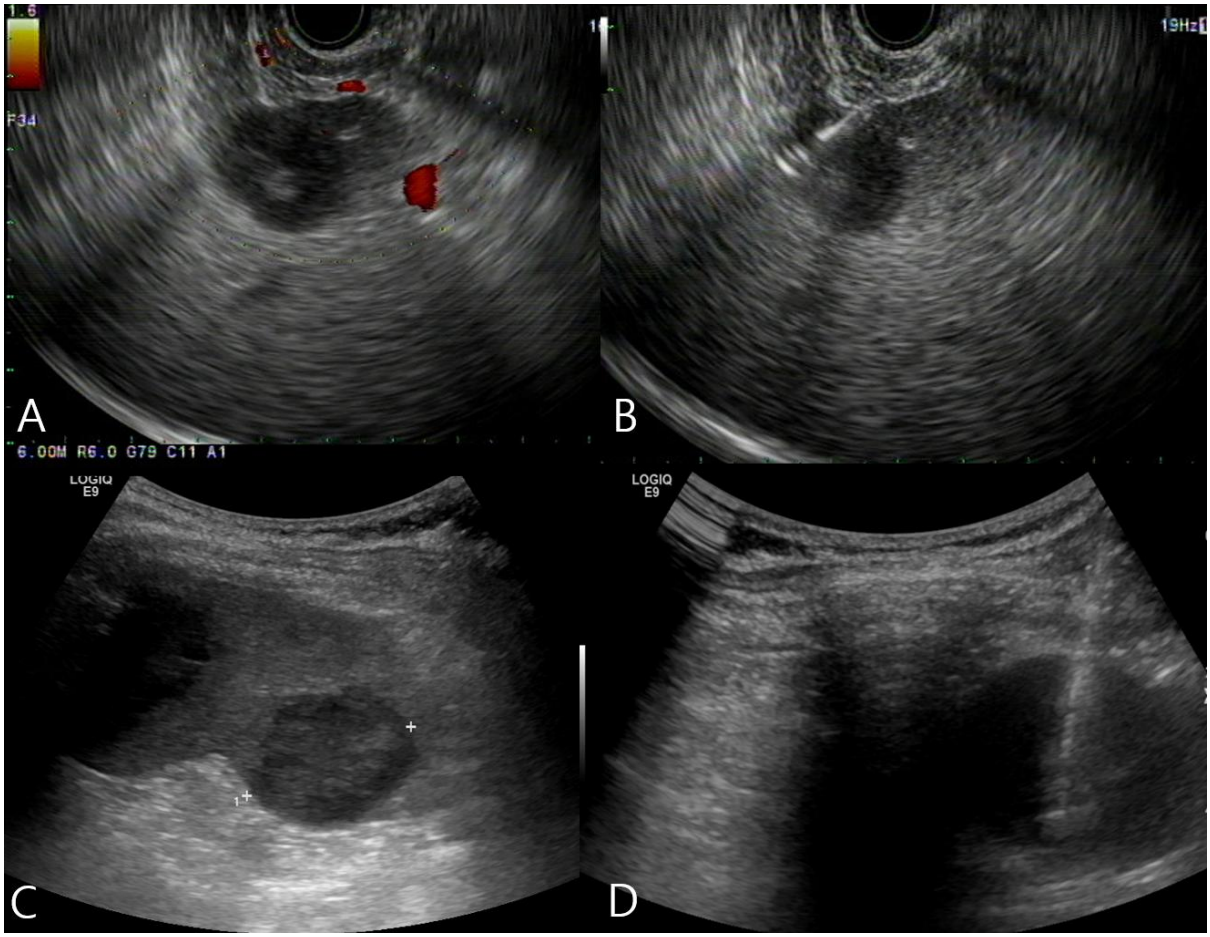
Definitions

All adverse events were classified as major or minor according to the guidelines of the Standards of Practice Committee.[18] Minor adverse events were defined as those requiring no or minimal therapy, including asymptomatic bleeding identified on post-procedural imaging (e.g., small subcapsular splenic hematomas). Major adverse events were defined as those requiring major therapeutic management, such as urgent radiologic, endoscopic, or operative intervention.

Statistics

Data were compared using Student's *t*-tests, Chi-square tests, and Fisher's exact tests. Sensitivity, specificity, accuracy, PPV, and NPV were calculated. Statistical analyses were performed using SPSS 12.0 for Windows (SPSS Inc., Chicago, IL). A P value <0.05 was considered statistically significant.

Figure 1. Endoscopic ultrasound showing the splenic mass through the transgastric route (A). EUS-guided spleen biopsy was performed (B). Abdominal ultrasonography revealed a splenic mass (C). A percutaneous biopsy was performed (D).



Results

A total of 60 patients (36 in the EUS group and 24 in the percutaneous group) were included in the analysis. The mean ages were 54.5 and 56.3 years old for the EUS and percutaneous groups, respectively. The mean platelet counts and prothrombin times (international normalized ratio) were within the normal ranges for both groups. The numbers and sizes of the splenic lesions were not significantly different between the groups. Puncture needles were 18-G (gauge) in 100% of the percutaneous group. Puncture needles in the EUS group were 19-G in 13.9% (5 cases) of patients, 20-G in 11.1% (4 cases) of patients, and 22-G in 75% (27 cases) of patients. The median lesion size was 27.0 mm (range, 18–53) in the EUS group and 27.5 mm (range, 17–45) in the percutaneous group. More than two needle passes were performed in 64.5% of the patients in the EUS group and 52.1% of the patients in the percutaneous group. Only one needle pass was allowed due to adverse events during the procedure (two hemorrhages and one abdominal pain) in three patients in the percutaneous group. Patient characteristics and baseline features for each technique are summarized in Table 1.

Twenty-one (35%) diagnoses were malignant, including 15 cases of lymphoma, four metastatic carcinomas (two esophageal cancers, one pancreatic cancer, and one ovarian cancer), one angiosarcoma, and one pleomorphic rhabdomyosarcoma. Lymphoma was diagnosed in 6 of the 36 patients in the EUS group (16.7%) and 9 of the 24 patients in the percutaneous group (37.5%). Benign conditions were present in 22 cases in the EUS group (61.1%) and 8 cases in the percutaneous group (25.0%). The most common benign diagnosis was hemangioma (6 cases, 10%). Nondiagnostic results included normal splenic parenchyma and insufficient tissue for diagnosis. Nondiagnostic outcomes occurred in 5 (13.9%) cases in the EUS group and 4 (16.7%) cases in the percutaneous group. Table 2 summarizes the histopathologic diagnoses. The sensitivity, specificity, and accuracy were 90.0%, 100%, and 96.8% in the EUS group and 92.3%, 100%, and 95.0% in the percutaneous group (Table 3).

Adverse events were reported in 20.8% of the patients in the percutaneous group. The rate of adverse events was significantly lower in the EUS group (8.3%) compared with the rate in the percutaneous group. Major adverse events occurred in 2 patients (8.3%) in the percutaneous group. In one patient with hemoperitoneum, transcatheter arterial embolization

and urgent splenectomy were performed due to hemorrhage. The other patient had a hemoperitoneum requiring heavy blood transfusion and intensive care unit admission. No major adverse events occurred in the EUS group.

Table 1. Baseline features of 60 patients who underwent spleen biopsies

Group	EUS (N = 36)	Percutaneous (N = 24)	p
Sex			0.188
F	21 (58.3%)	9 (37.5%)	
M	15 (41.7%)	15 (62.5%)	
Age (yrs)	54.5 ± 13.3	56.3 ± 16.2	0.502
WBC	6.2 ± 1.6	5.7 ± 1.9	0.398
Hemoglobin, g/dL	12.6 ± 1.6	11.3 ± 2.3	0.015
Platelet, $\times 10^5/mm^3$	223.2 ± 70.3	185.3 ± 65.4	0.040
PT (INR)	1.0 ± 0.1	1.0 ± 0.2	0.107
Number of lesions			
Multiple	17 (47.2%)	12 (50.0%)	0.667
Single	19 (52.8%)	10 (41.7%)	
Splenomegaly	0 (0%)	2 (8.3%)	
Size of the target lesion (mm) [range]	27.0 [18.0–53.0]	27.5 [17.0–45.0]	0.537
Needle gauge			
18-gauge	0 (0.0%)	24 (100%)	
19-gauge	5 (13.9%)	0 (0.0%)	<0.001
20-gauge	4 (11.1%)	0 (0.0%)	
22-gauge	27 (75.0%)	0 (0.0%)	
Number of needle passes			
1	0 (0.0%)	3 (13.0%)	
2	11 (30.6%)	8 (34.8%)	0.102
3	19 (52.8%)	11 (47.8%)	
4	6 (16.7%)	1 (4.3%)	
Sample processing			
Histology	14 (38.9%)	24 (100.0%)	<0.001
Histology+Smear cytology	21 (58.3%)	0 (0.0%)	
Smear cytology	1 (2.8%)	0 (0.0%)	

Table 2. Histopathologic results of splenic biopsies in 60 patients

	EUS (N = 36)	Percutaneous (N = 24)
Malignant	9 (25.0%)	12 (50.0%)
Diffuse large B cell lymphoma	5	4
Follicular lymphoma	1	4
Peripheral T cell lymphoma		1
Angiosarcoma		1
Pleomorphic rhabdomyosarcoma		1
Metastatic carcinoma		
Esophageal cancer	1	1
Pancreatic cancer	1	
Ovarian cancer	1	
Benign	22 (61.1%)	8 (33.3%)
SANT	3	
Granulomatous inflammation		1
Sarcoidosis	3	
Tuberculosis	1	2
Hemangioma	5	1
Hamartoma	2	1
Epidermoid cyst	1	
Epithelial cyst	1	
Lymphoepithelial cyst	1	
Hemorrhagic mass	1	
Abscess	2	1
Inflammatory pseudotumor	2	1
Splenic congestion		1
Nondiagnostic	5 (13.9%)	4 (16.7%)

Table 3. Diagnostic accuracy of endoscopic ultrasound spleen biopsies (N = 36) and percutaneous spleen biopsies (N = 24)

	Sensitivity	Specificity	Accuracy	PPV	NPV
EUS	9/10 (90.0%)	21/21 (100%)	30/31 (96.8%)	9/9 (100%)	21/22 (95.5%)
Percutaneous	12/13 (92.3%)	7/7 (100%)	19/20 (95.0%)	12/12 (100%)	7/8 (87.5%)

Table 4. Adverse events of spleen biopsies

	EUS (N = 36)	Percutaneous (N = 24)	*P*-value
Total adverse events	3 (8.3%)	5 (20.8%)	0.023
Major adverse events			
Hemoperitoneum		2 (8.3%)	
Minor adverse events			
Mild tract bleeding		2 (8.3%)	
Small subcapsular hematoma	2 (5.6%)		
Mild mucosal bleeding	1 (2.8%)		
Abdominal pain during biopsy		1 (4.2%)	

Discussion

Spleen biopsies provide essential clinical information regarding the diagnosis and management of various splenic diseases. Many hematopoietic diseases can cause splenic infiltration with splenomegaly and splenic focal lesions. Splenic involvement in lymphoma occurs in up to 40% of patients.[19] In many cases, lymphoma is diagnosed with a biopsy of the enlarged lymph nodes; however, primary splenic lymphomas have localized lesions, with no lymph node involvement.[20] As the histological type determines the prognosis and chemotherapy regimen for lymphoma, tissue samples from the spleen are essential for definitive diagnoses. In this study, fifteen (25%) of 60 diagnoses were lymphomas; diffuse large B cell lymphoma (9/60, 15%) was the most frequent diagnosis and follicular lymphoma (5/60, 8.3%) was the second most frequent diagnosis.

Although the spleen is an infrequent site for metastatic lesions, some solid tumors metastasize to the spleen. Common primary cancers that metastasize to the spleen include breast, lung, ovary, stomach, prostate, and melanoma cancers.[4] Peritoneal implants on the splenic surface may occur in ovarian, gastrointestinal, and pancreatic cancers.[4] Esophageal cancer is a rare cause of splenic metastasis, and only a few cases have been reported.[21] In this study, two of the four splenic metastases were from esophageal cancer.

As shown in Table 2, various benign lesions involve the spleen, including benign splenic cysts such as epithelial, epidermoid, and lymphoepithelial cysts. Hemangiomas and sclerosing angiomatoid nodular transformation (SANT) are also benign vascular lesions involving the spleen.[22] Splenic hemangiomas are the most frequent benign tumor of the spleen and SANT is a non-neoplastic vascular lesion with a typical radiographic appearance.[22] Infectious and inflammatory conditions also cause splenic lesions. Splenic abscesses are usually caused by hematogenous spread from other sources, such as pneumonia and gastrointestinal infections.[22] Granulomatous infections with Mycobacterium tuberculosis usually occur in the miliary form caused by hematogenous dissemination. Fungal abscesses, such as candidiasis, can occur in patients with prolonged febrile neutropenia.[23] Sarcoidosis, which is a multisystemic disease with noncaseating granulomas, can also involve the spleen and manifests as splenomegaly or focal lesions.

Traditional methods of acquiring splenic tissue include percutaneous biopsies and splenectomies. However, splenectomy and percutaneous biopsies carry risks of serious adverse events and complications. More recently, the EUS-guided biopsy technique has evolved as a safe and effective alternative method of tissue sampling. EUS-fine needle aspiration (FNA) was first reported by Vilmann et al. as a biopsy method for pancreatic tumors in 1992.[24] Thereafter, the indication for the procedure expanded to other intra-abdominal organs and lymph nodes, significantly contributing to the diagnosis and treatment of various diseases. Compared to percutaneous routes, EUS-guided biopsies have a greater diagnostic yield of tissue, are superior for targeted approaches to focal lesions, provide higher quality images, and allow for greater patient comfort.[25] Fritscher-Ravens et al. first reported the use of EUS-FNA for diagnosing splenic lesions.[13] EUS enables closer observation of the spleen through the gastric wall and facilitates easy recognition of surrounding organs.[13] Additionally, EUS-guided biopsies are conducted under sedation, allowing for reduced procedural anxiety and increased patient comfort.[25] These advantages have contributed to the increased use of EUS-guided biopsies for obtaining spleen tissue.

The use of core biopsy needles for EUS-guided spleen biopsies enables histopathological analysis and immunochemical staining of larger samples.[14] The use of EUS-guided biopsies with a 19-gage needle was previously reported, and 22-gage needles are useful in diagnosing splenic tumors, such as lymphomas.[17,26,27] In our study, the diameter of the puncture needle was determined by the endoscopists. As shown in Table 1, 22G, 20G, and 19G needles were used in 75% 11.1%, and 13.9% of patients in the EUS group. A 22G needle was efficacious and safe for EUS-guided spleen biopsies in this study but larger studies are needed to determine the appropriate puncture needle diameter for spleen biopsies.

For our analysis, insufficient tissue for diagnosis and normal splenic parenchyma were categorized as nondiagnostic. These nondiagnostic biopsies were not included in the calculations of sensitivity, specificity, accuracy, PPV, and NPV. A previous meta-analysis of percutaneous image-guided spleen biopsies showed a sensitivity of 87% and a specificity of 96.4%.[11] In this study, the sensitivity, specificity, and accuracy were 90.0%, 100%, and 96.8% for the EUS group and 92.3%, 100%, and 95.0% for the percutaneous group, respectively (Table 3). Two false negative biopsies were observed, one in each group. One patient in the EUS group subsequently underwent splenectomy and was diagnosed with diffuse large B cell

lymphoma, and one patient in the percutaneous group was subsequently diagnosed with T cell lymphoma with a liver biopsy.

Historically, spleen biopsies are not frequently performed due to the associated risk of bleeding. This reluctance may be related to an early report demonstrating a high major complication rate for percutaneous biopsies of the spleen performed with a 14-G core needle.[9] Several recent publications reported much lower complication rates using needles with smaller diameters.[2,10,11] However, serious bleeding events requiring transcatheter arterial embolization or urgent splenectomy still occur after percutaneous biopsy with smaller diameter needles.[10,12] In our study, major adverse events occurred in 2 patients in the percutaneous group. One of them required transcatheter arterial embolization and splenectomy due to hemorrhage, and the other patient needed a heavy transfusion and intensive unit care admission. In contrast, no major adverse events occurred in the EUS group, and the overall complication rate was significantly lower in the EUS group compared with the rate in the percutaneous ($p = 0.023$). Although the total adverse event rate for both groups (EUS: 8.3%, percutaneous: 20.8%) was higher than previous reports, most adverse events were minor, such as minor mucosal and tract bleeding during or after the procedure. Minor adverse events are difficult to identify unless imaging follow-up is routinely performed. In our practice, a post-procedure scan was performed to ensure that there was no internal bleeding immediately after the procedure. However, imaging, such as CT, was not routinely performed and was only indicated if there was a clinical concern. The post-procedure follow-up protocols varied among the previous studies.

One percutaneous biopsy procedure was stopped due to severe abdominal pain after one needle pass. Some disadvantages of percutaneous biopsy are pain and apprehension in patients, as the procedure is performed under minimal or no sedation. On the other hand, EUS-guided biopsy is usually performed under sedation and patient comfort is increased.[15]

In this study, the safety profile and diagnostic adequacy were similar between EUS-guided biopsies and percutaneous biopsies. The overall rate of adverse events was significantly lower in the EUS group compared with the percutaneous group; no major bleeding adverse events occurred in the EUS group. This study is the first study comparing EUS-guided spleen biopsies with percutaneous spleen biopsies. This study had several limitations. This was a

single-center, small, retrospective study. Procedures regarding the biopsy technique were incompletely documented. All adverse events were identified retrospectively and may not have been completely captured. Large-scale randomized comparative clinical trials are needed to compare the safety and efficacy of EUS-guided spleen biopsies to that of percutaneous biopsies.

Conclusion

EUS spleen biopsies are safe and accurate, with high diagnostic accuracy. The risk of bleeding may be lower with EUS biopsies compared with the risk with percutaneous biopsies.

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국문 요약

배경: 비장의 국소 병변의 진단을 위해서 경피적 조직 검사 방법이 가장 흔하게 사용되어왔다. 하지만 경피적 조직 검사 방법은 조직 검사 후 심각한 출혈과 같은 합병증에 대한 우려가 있어 널리 사용되고 있지는 못한 상황이다. 내시경초음파 유도하 조직 검사법은 또 다른 비장 조직 검사 방법 중 하나로 최근 경피적 조직 검사 방법의 대안으로 관심 받고 있다. 내시경초음파 유도하 비장 조직 검사와 경피적 비장 조직 검사를 비교한 연구가 없던 바, 본 연구에서는 두 조직 검사 방법의 유용성과 안전성을 비교해 보고자 한다.

대상과 방법: 본 연구는 후향적 연구로서 2015년부터 2021년까지 단일 상급종합병원에서 비장 병변에 대한 조직학적 진단을 위해 내시경초음파 유도하 또는 경피적 초음파 유도하 조직 검사를 시행한 총 60명의 환자를 대상으로 하였다. 이 환자들을 두 군으로 나누고 두 환자군 간에 임상적 결과 및 합병증에 차이가 있는지 평가해 보았다.

결과: 총 60명의 환자에서 비장 조직 검사를 시행하였다. 그 중 36명에서는 내시경초음파 유도하 조직 검사를 시행하였고, 나머지 24명에서는 경피적 조직 검사를 시행하였다. 내시경초음파 유도하 조직 검사 군에서 민감도, 특이도, 정확도는 각각 90.0%, 100%, 96.8%였고, 경피적 조직 검사 군에서는 92.3%, 100%, 95.0% 였다. 60명의 환자 중 21명 (35%)이 악성으로 진단되었고, 가장 흔한 진단은 림프종 (lymphoma) 였다. 중대한 합병증은 경피적 조직 검사 군에서 2명 발생하였고, 그 중에 한 명은 중증 출혈로 경동맥 색전술과 응급 비장 절제술이 필요하였다. 내시경초음파 유도하 조직 검사 군에서는 중대한 합병증은 없었고 전체 합병증 발생율도 경피적 조직 검사 군에 비해 유의하게 낮았다

(*p*=0.023).

결론: 내시경초음파 유도하 비장 조직 검사는 높은 진단적 정확성을 가진 안전하고 정확한 검사 방법이다. 경피적 조직 검사와 비교해서 내시경초음파 유도하 조직 검사는 합병증의 위험이 더 적었으므로 합병증의 위험이 높을 것으로 생각되는 환자에게 경피적 조직검사의 대안으로 고려될 수 있을 것이다.