IC-KPBA 2020
International Conference
of the Korean Pancreatobiliary Association 2020

A Prospective, Multi-center, Comparative Study to Evaluate a New Needle in EUS-TS for Pancreatic Solid Lesions

Chang Min Cho[1], Jae Hee Cho[2], Jong Jin Hyun[3], Sang Myung Woo[4], Dong Wook Lee[5], Jun-Ho Choi[6], Kwang Hyuck Lee[7], Sang Hyub Lee[8], Tae Jun Song[9], Chang Hwan Park[10], Eunae Cho[10], Seong-Hun Kim[11], Se Woo Park[12], Tae Hyeon Kim[13], Research Group for Endoscopic Ultrasonography

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[9]Department of Internal Medicine, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea
[10]Department of Internal Medicine, Chonnam National University Hospital, Gwangju, Korea
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[12]Division of Gastroenterology, Department of Internal Medicine, Hallym University Dongtan Sacred Heart Hospital, Hallym University College of Medicine, Gyeonggi-do, Korea
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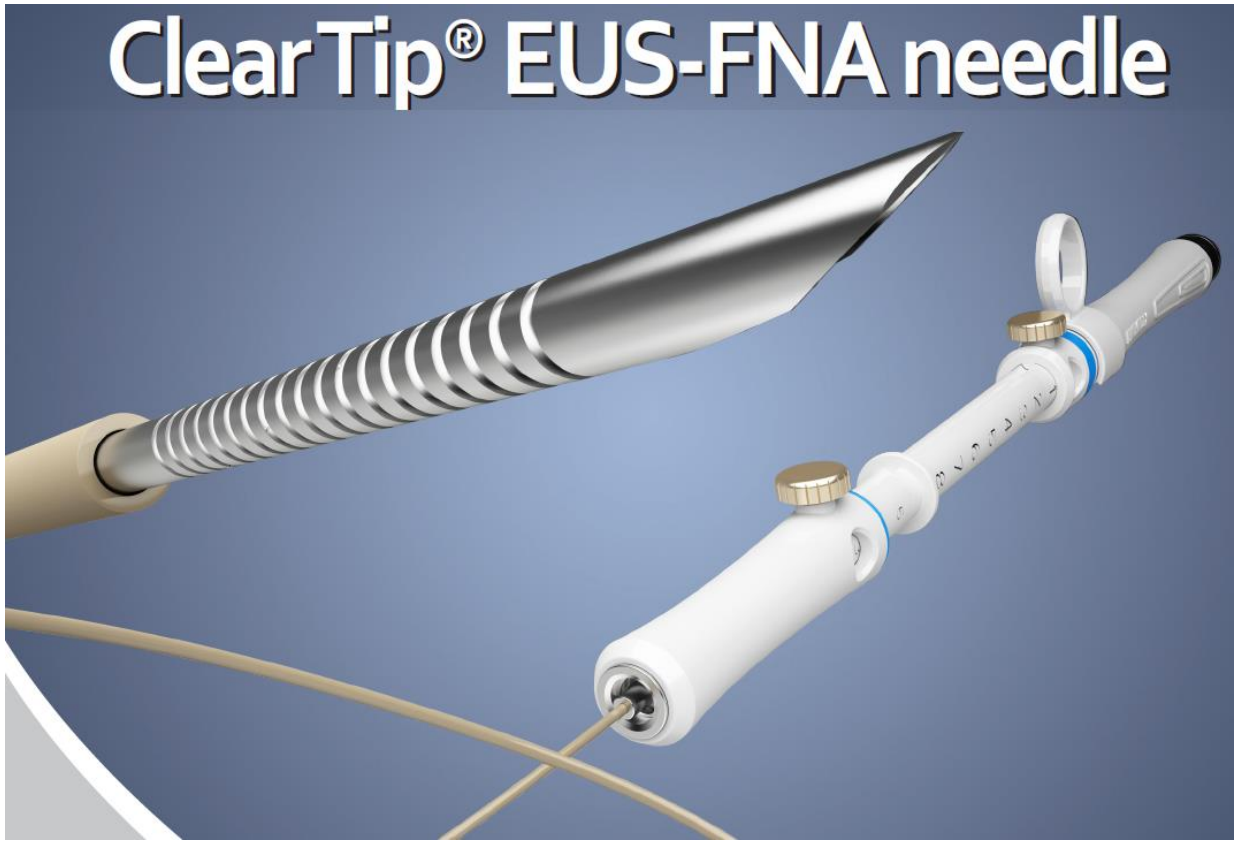
This study was sponsored from Korea Health Industry Development Institute as supportive project for the evaluation of new product of domestic medical device (2019).

Introduction

- Evaluation of pancreatic solid lesions
  - Histologic confirmation: crucial
  - EUS-guided tissue sampling: standard procedure
- Ideal EUS-TS needle
  - Procurement of adequate specimen
  - Including core tissue for further IHC study
  - Technically easy (esp, transduodenal approach)
  - Not expensive

Introduction

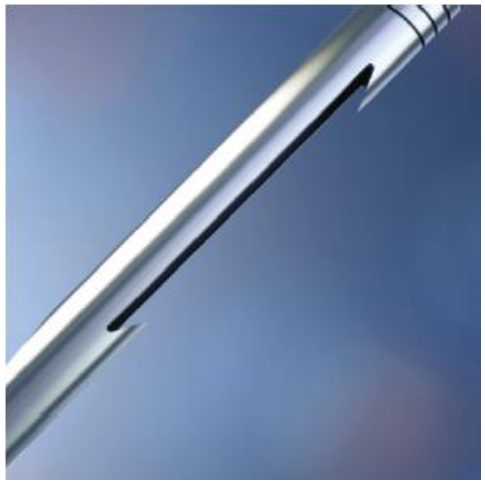
- EUS-TS needles
  - Variable brands with
    - Different size
    - Different shape
  - Currently dependent on foreign product
  - Expensive (?)
- Until now, no domestic product for EUS-TS



Model	Needle Tube Shape	Needle Diameter (G)	Max. Needle Length(mm)	Working Length(mm)
FM-CTA001	A Type	19	76	1,430
FM-CTA002		22		
FM-CTA003		25		
FM-CTB001	B Type	19		
FM-CTB002		22		
FM-CTB003		25		

Spiral Echo Shape

Well visible echo pattern on EUS image makes easy positioning of the needle.



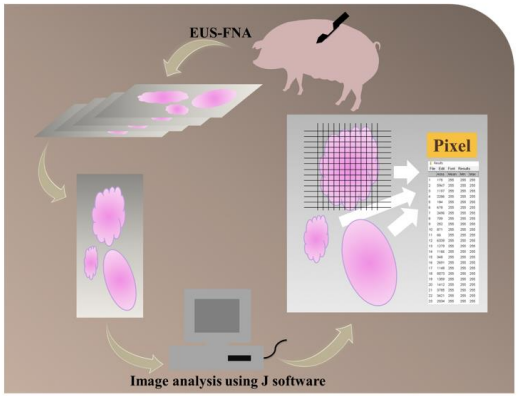
Quantitative Analysis of the Specimen acquired from EUS-FNA; The Preclinical Evaluation of New Needles in Porcine Liver

Myung Hi Kim[1], Seong Jae Yeo[1], Chang Min Cho[1], An Na Seo[2], Jun Sik Kim[3]

Department of [1]Internal Medicine and [2]Pathology, Kyungpook National University Medical Center, Daegu, South Korea

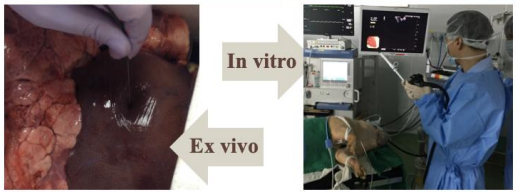
[3]Laboratory Animal Center (LAC), Daegu-Gyeongbuk Medical Innovation Foundation (DGMIF), Daegu, South Korea

36.5 KNUMC
KYUNGPOOK NATIONAL UNIVERSITY MEDICAL CENTER

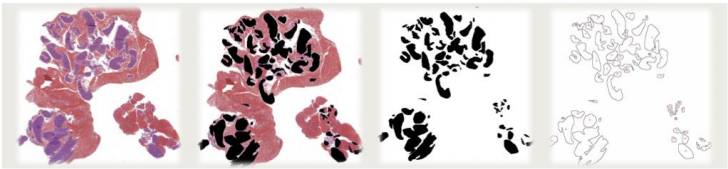


- **In phase 1 study (Ex vivo)**
- Fine needle aspiration was performed in the extracted pig liver.
- Randomly applied to acquire FNA specimen
  - Comparison depending on needle size: new needles of 19, 22, and 25-gauge
  - Comparison depending on manufacturers of needle
  : 4 different types of conventional needles of 22-guage vs Clear-Tip® needle

- **In phase 2 study (In vitro)**
- EUS-guided tissue sampling for liver in the anesthetized pig was performed.
- Using linear echoendoscope (GF-UCT260, Olympus Korea)
- 4 different types of needles with 22-gauge and Clear-Tip® needle with 22-gauge were used.

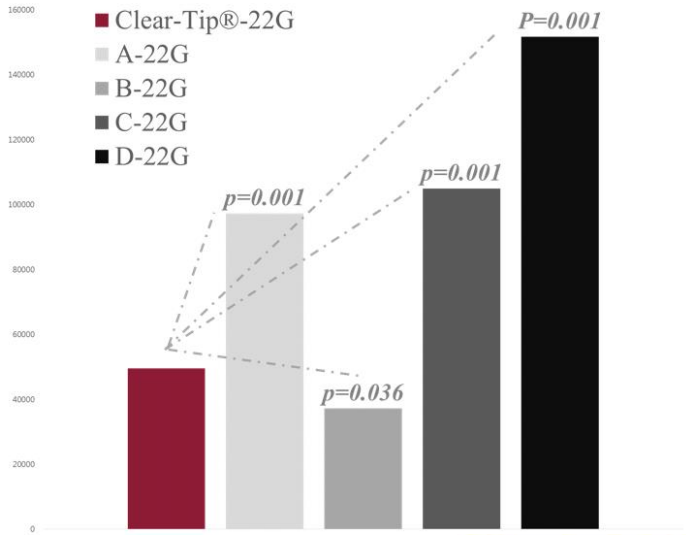


- **Data summation**
- Using computerized analysis (J software) of the scanned histologic slide
- The area of liver tissue in specimens obtained from variable needles was compared.

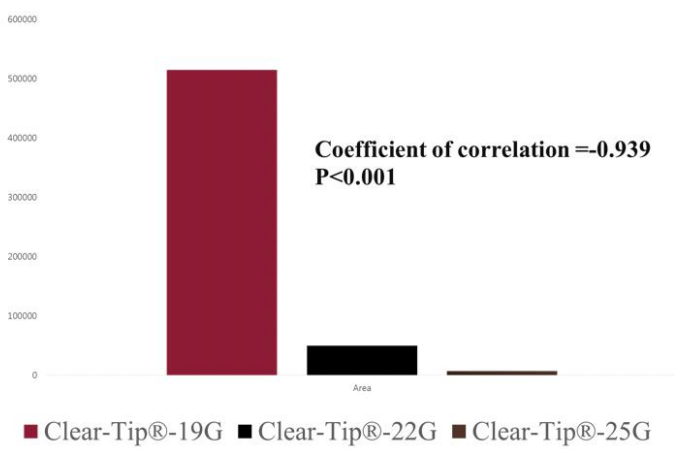


Phase 1 study(Ex vivo)

❖ Comparison of EUS-FNA specimens depending on manufacture of 22G conventional needle in porcine liver

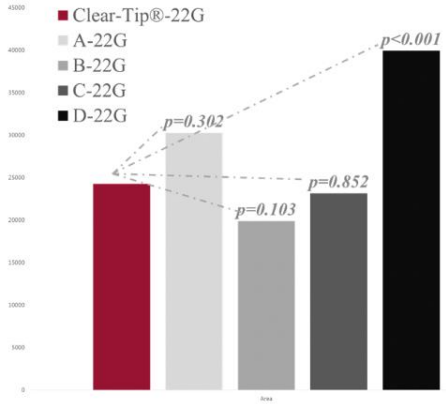


❖ Comparison of EUS-FNA specimens depending on needle size of Clear-Tip® in porcine liver

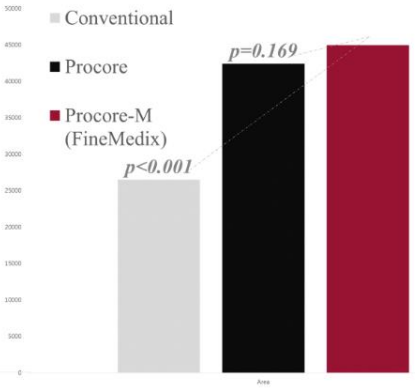


Phase 2 study(In vitro)

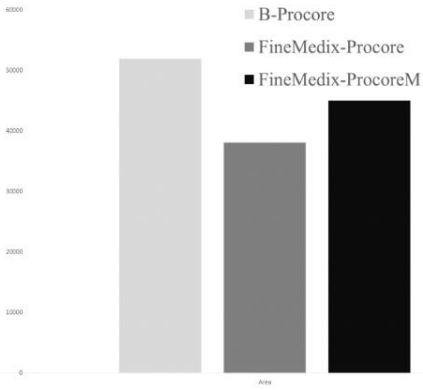
❖ Comparison of EUS-FNA specimens depending on manufacture of conventional needle in porcine liver



❖ Comparison of EUS-FNA specimens depending on needle type in porcine liver

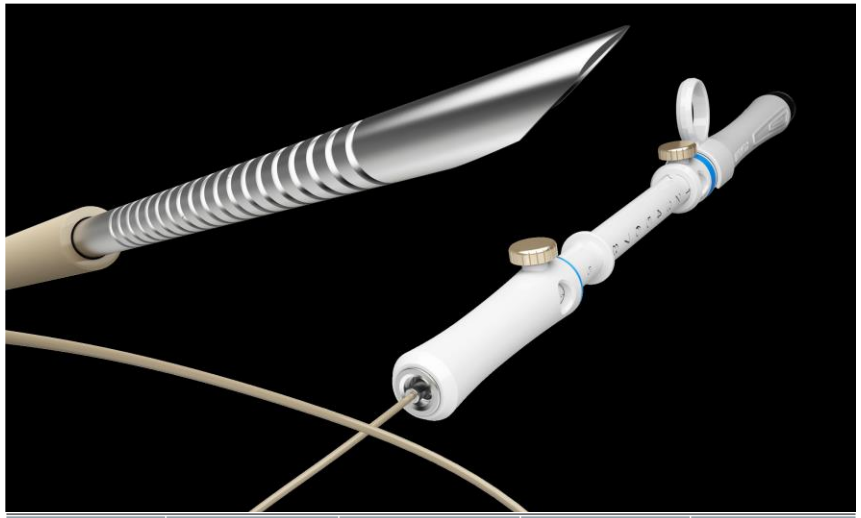


❖ Comparison of EUS-FNA specimens between 22G ProCore needle of B-manufacture and FineMedix in porcine liver



ClearTip® EUS-FNA needle

www.finemedix.com



Model	Needle Tube Shape	Needle Diameter (G)	Max. Needle Length(mm)	Working Length(mm)
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FM-CTB003		25		

C-Ring

This component can be de-and attached for the convenience of the user, and facilitates tissue and cell collecting by applying proper force.

Spiral Echo Shape

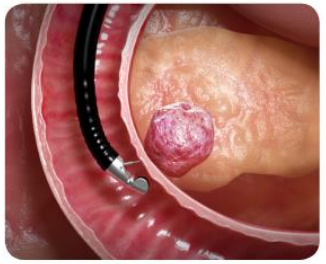
Well visible echo pattern on EUS image makes easy positioning of the needle.

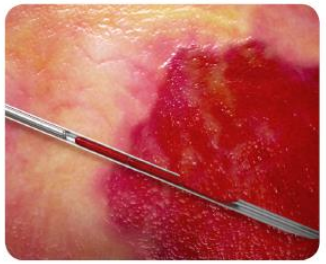
FNA (A type)

The back-cut needle is designed for precise targeting and easy insertion into the lesion.

FNAB (B type)

During to and fro motion in the lesion, this special type needle (both back cutted bevel) can acquire more tissue with less handling.





식품의약품안전처 신제품 등록

☐ 신청제품 정보

품목명	일회용내시경생검용기구(2등급)		
제품명	ClearTip		
식약처 제조허가번호	제인 17 - 4544 호	제품 출시년월	2017 년 7월
제품 인허가 현황	■ CE(EU) ■ FDA(美) ☐ CFDA(中) ☐ PMDA(日) ☐ 기타 ( )		

Free Paper (Endoscopy-PB 1)
2018-11-17 14:00~14:10

Feasibility and efficacy of a novel needle in endoscopic ultrasound-guided tissue sampling for pancreatic solid lesions: A prospective randomized comparative study

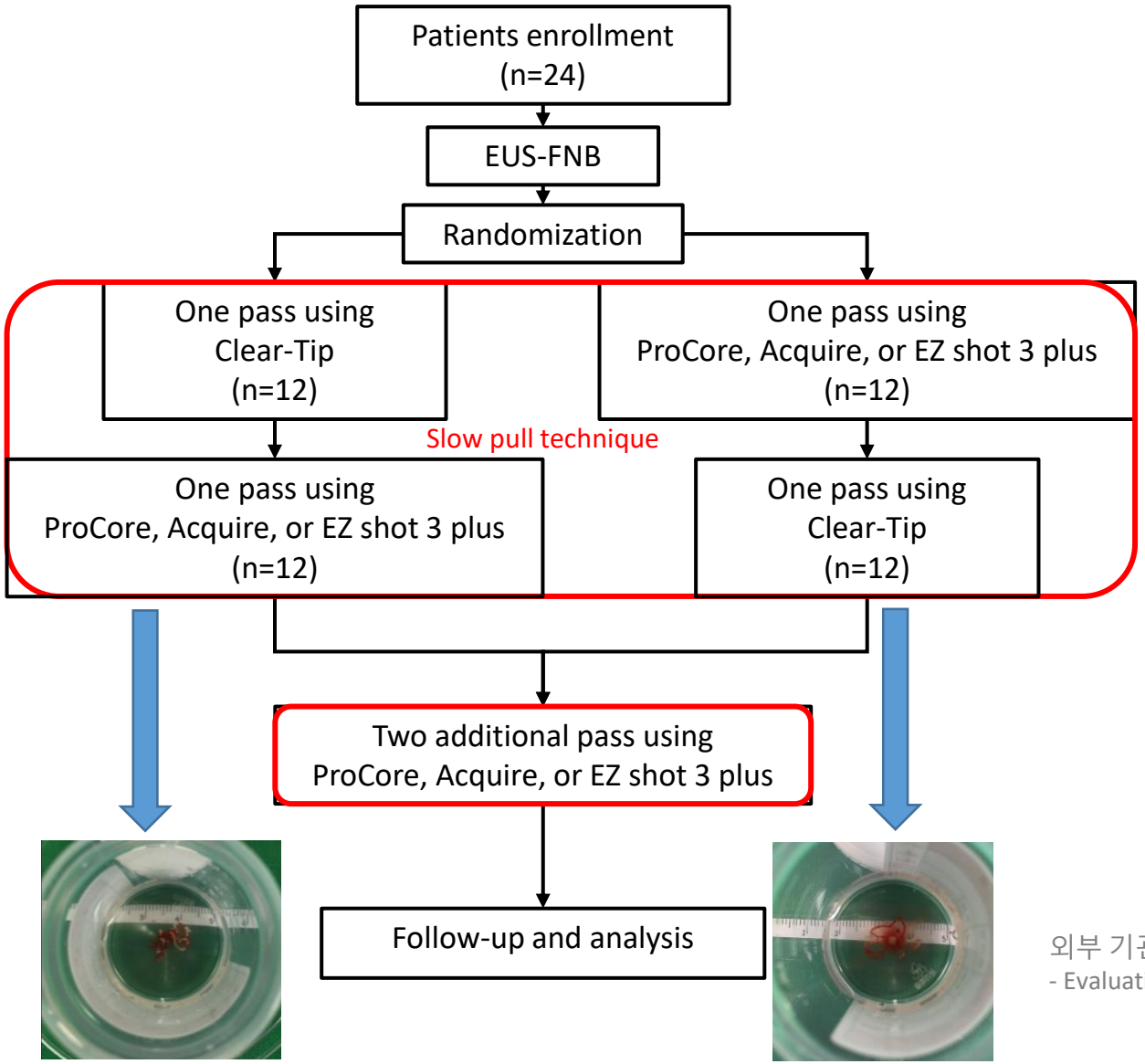
Chang-Min Cho[1], Seong Jae Yeo[1], Han Ik Bae[2], An Na Seo[2]

Department of Internal Medicine[1] and Pathology[2]

School of Medicine, Kyungpook National University

Kyungpook National University Chilgok Hospital, Daegu, South Korea

Study algorithm



Primary outcome
- Diagnostic performance

Secondary outcome
- Specimen adequacy

For diagnostic standard

외부 기관에 병리 슬라이드 scanning 의뢰
- Evaluation of specimen adequcy

Result

New prototype needle

- Low diagnostic yield at transduodenal approach
- Need to make improvements

- Study duration: Feb. 2018 ~ Jun. 2018
- 24 patients with pancreatic solid lesions

Variables	N=24
Age, year, median (range)	63.5 (38~87)
Male:Female	14:10
Site, n (%) Uncinate/head/neck body/tail	 1 (4.2)/ 4 (16.7)/ 7 (29.2) 9 (37.5)/ 3 (12.5)
Size, mm, mean ± SD	32.4 ± 2.8

Final diagnosis	No. (%)
Benign	
Chronic pancreatitis	1 (4.2)
Autoimmune pancreatitis	1 (4.2)
Malignancy	
Pancreatic ductal adenocarcinoma	19 (79.2)
Neuroendocrine tumor	1 (4.2)
Metastasis	1 (4.2)
Unknown	1 (4.2)

One patient: no final diagnosis

Technical failure in one patients using test needle

	Test needle (n=22)	Control needle (n=23)	P value
Specimen adequacy	21 (95.5%)	22 (95.7%)	0.245

Diagnostic accuracy	Test needle (n=23)	Control needle (n=23)	P value
Overall	16 (69.6%)	19 (82.6%)	0.491
Transgastric	10 (83.3%)	10 (83.3%)	1.000
Transduodenal	6 (54.5%)	9 (81.8%)	0.361

2019년 춘계학술대회
일시 : 2019년 4월 27일 (토요일)
장소 : 여의도 콘래드 호텔

대한췌장담도학회
Korean Pancreatobiliary Association

Oral Presentation Session II
2019-04-27 14:00~14:10

The Evaluation of Specimen Adequacy and Diagnostic Performances using an Improved Novel Needle in Endoscopic Ultrasound-guided Tissue Sampling for Pancreatic Solid Lesions: A Prospective Randomized Comparative Study

Chang-Min Cho[1], Seong Jae Yeo[1], Han Ik Bae[2], An Na Seo[2]

Department of Internal Medicine[1] and Pathology[2]

School of Medicine, Kyungpook National University

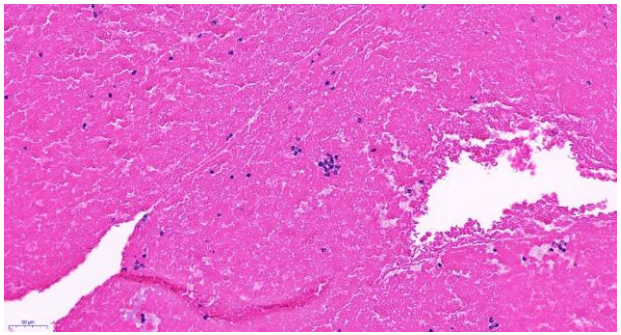
Kyungpook National University Chilgok Hospital, Daegu, South Korea

Evaluation of histologic specimen

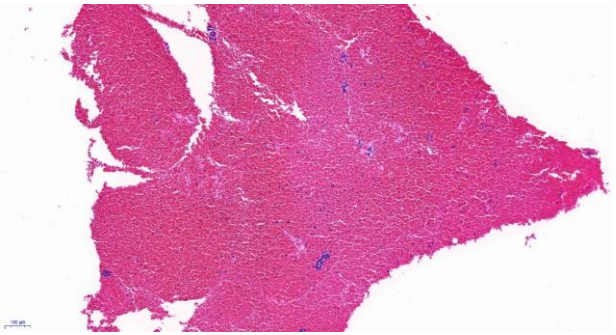
- Two expert pathologist
  - No clinical information
  - No information of used needle
  - Interpretation of each slide
    - Malignancy, suspicious for malignancy, atypical, benign, inadequate
  - Scoring system for specimen adequacy
- Diagnostic standard
  - Malignancy for any EUS-TS specimen
  - Malignancy for other specimen
  - Surgical pathology
  - Clinical follow up (> 6 months) in benign diseases

Microscopic scoring

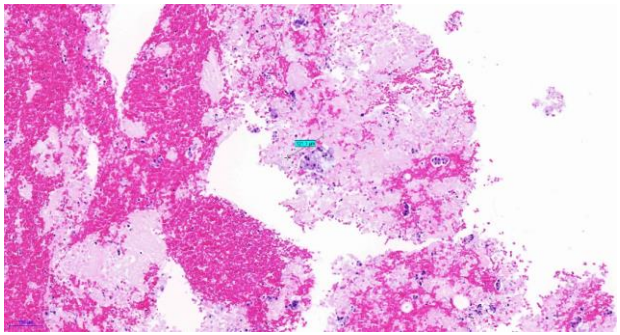
0: No cell or blood clots only



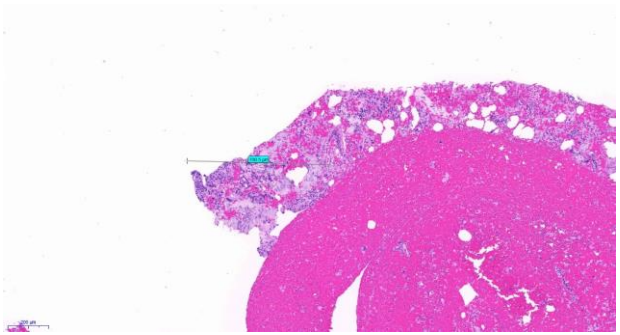
1: Insufficient material for limited cytological interpretation; probably not representative



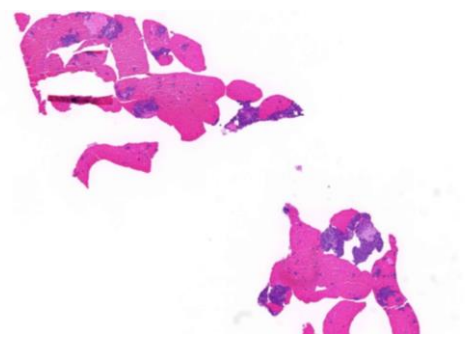
2: Sufficient material for adequate cytological interpretation



3: Sufficient material for limited histological interpretation (core tissue < 500 um at minimal length)



4: Sufficient material for low quality histological interpretation (1 core tissue of > 500 um at minimal length)



5: Sufficient material for good quality histological interpretation (> 1 core tissue of > 500 um at minimal length)

Result

- Study duration: Aug. 2018 ~ Oct. 2018
- 24 patients with pancreatic solid lesions

Variables	N=24
Age, year, median (range)	70.5 (32~84)
Male:Female	8:16
Site, n (%) Uncinate/head/neck body/tail	 0/ 9 (37.5)/ 3 (12.5) 10 (41.7)/ 2 (8.3)
Size, mm, mean ± SD	27.6 ± 9.5

Final diagnosis	No. (%)
Benign	
Chronic pancreatitis	1 (4.2)
Autoimmune pancreatitis	1 (4.2)
Malignancy	
Pancreatic ductal adenocarcinoma	18 (75.0)
Neuroendocrine tumor	3 (12.4)
Metastasis	1 (4.2)

Results

Diagnostic accuracy	Test needle (n=24)	Control needle (n=24)	P value
Overall	21 (87.5%)	20 (83.3%)	1.000
Transgastric	11 (91.7%)	9 (75.0%)	0.590
Transduodenal	10 (83.3%)	11 (91.7%)	1.000

Score	Test needle (n=24)	Control needle (n=24)	Test needle (n=24)	Control needle (n=24)	P value
0	0	1 (4.2%)	11 (45.8%)	8 (33.3%)	0.556
1	1 (4.2%)	1 (4.2%)			
2	3 (12.5%)	1 (4.2%)			
3	7 (29.2%)	5 (20.8%)			
4	1 (4.2%)	1 (4.2%)	13 (54.2%)	16 (66.7%)	
5	12 (50.0%)	15 (62.5%)			

Diagnostic accuracy

Phase		Test	Control	P value
I	Overall (n=23)	16 (69.6%)	19 (82.6%)	0.245
	Transgastric	10 (83.3%)	10 (83.3%)	0.705
	Transduodenal	6 (54.5%)	9 (81.8%)	0.181
II	Overall (n=24)	21 (87.5%)	20 (83.3%)	1.000
	Transgastric	11 (91.7%)	9 (75.0%)	0.590
	Transduodenal	10 (83.3%)	11 (91.7%)	1.000
Total	Overall (n=47)	37 (78.7%)	39 (83.0%)	0.794
	Transgastric	21 (87.5%)	19 (79.2%)	0.701
	Transduodenal	16 (69.6%)	20 (87.0%)	0.284

Conclusion

- New improved prototype needle
  - Feasible and efficient for EUS-TS
  - Similar diagnostic yield at transduodenal approach
  - No technical failure

- Further study is needed including large volume involving multicenter for pancreatic lesions to validate the efficacy of new needle.

Study aims

- Multicenter, open-labeled, randomized clinical trials between an improved novel EUS-TS needle (22G, ClearTip™) and 22G ProCore needle in pancreatic solid lesions
  - Primary outcome: diagnostic performance
  - Secondary outcome
    - Technical success
    - Specimen adequacy

임상시험 참여 기관 및 책임자

No.	Institution	P.I.
1	칠곡경북대학교병원	조창민
2	가천의대 인천길병원	조재희
3	고려대학교 안산병원	현종진
4	국립암센터	우상명
5	대구가톨릭대학병원	이동욱
6	단국대학교병원	최준호
7	서울대학교병원	이상협
8	성균관대학교 삼성서울병원	이광혁
9	울산대학교 서울아산병원	송태준
10	전남대학교병원	박창환
11	전북대학교병원	김성훈
12	한림대학교 동탄성심병원	박세우
13	원광대학교병원	김태현

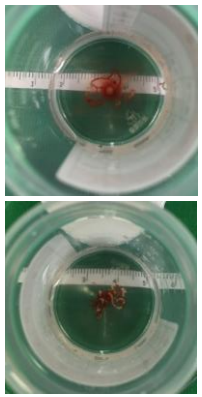
Study algorithm

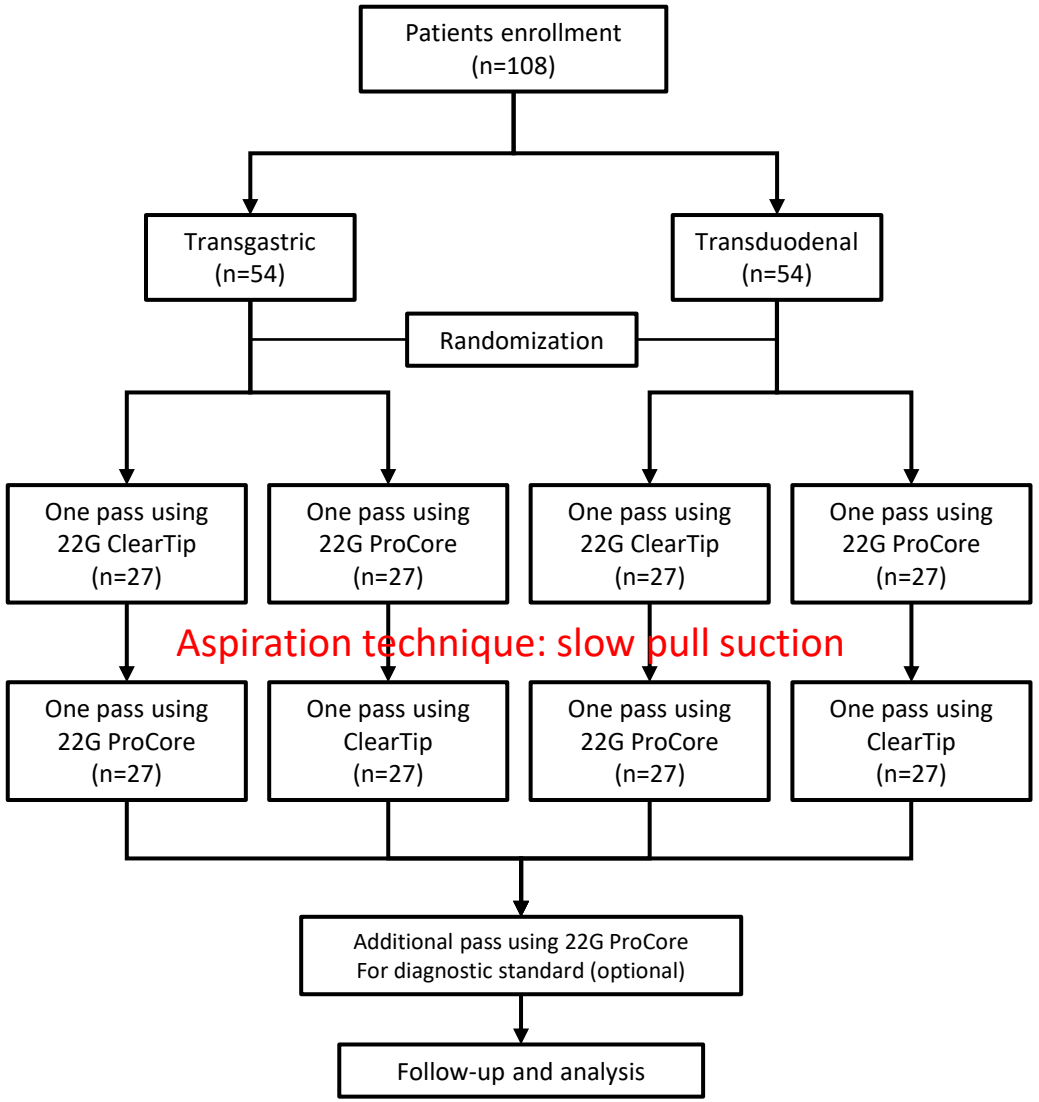
Primary outcome

- Diagnostic performance

Secondary outcome

- Specimen adequacy
- Technical success





Study design

- 22G ClearTip FNB needle vs. 22G ProCore needle
  - Each one needle pass in same patients
- Sample size calculation
  - Non inferior clinical trial
    - 2.5% type I error and 85% power (1-β)
    - Diagnostic yield in control needle: 85%
    - Non-inferiority margin: 15%
  - 108 samples including 5% exclusion

$$n_A = \kappa n_B \text{ and } n_B = \left(\frac{p_A(1-p_A)}{\kappa} + p_B(1-p_B) \right) \left(\frac{z_{1-\alpha/2} + z_{1-\beta}}{p_A - p_B} \right)^2$$

$$1-\beta = \Phi\left(z - z_{1-\alpha/2}\right) + \Phi\left(-z - z_{1-\alpha/2}\right) \quad , \quad z = \frac{p_A - p_B}{\sqrt{\frac{p_A(1-p_A)}{n_A} + \frac{p_B(1-p_B)}{n_B}}}$$

Clinical trial variables

3. Technical success interpretation

Pass	1st	2nd
Type of needle	☐ Test / ☐ Control	☐ Test / ☐ Control
Visibility of needle within lesion	☐ Good ☐ Bad ☐ Unknown	☐ Good ☐ Bad ☐ Unknown
Needle puncture into the target	☐ Easy ☐ Difficult ☐ Unknown	☐ Easy ☐ Difficult ☐ Unknown
Easy of to-and-fro motion	☐ Good ☐ Bad ☐ Unknown	☐ Good ☐ Bad ☐ Unknown
Needle angulation after FNB	☐ Presence ☐ Absence	☐ Presence ☐ Absence

1st pass	☐ Test / ☐ Control	
Gross core tissue	☐ Presence / ☐ Absence / ☐ Unknown	
Pathologic report		
Pathology class	☐ 0	Inadequate specimen
	☐ 1	Benign or no malignancy
	☐ 2	Atypical cells present
	☐ 3	Suspicious for malignancy
	☐ 4	Malignancy
Microscopic scoring	☐ 0	No cell or blood clots only
	☐ 1	Sufficient material for limited cytological interpretation; probably not representative
	☐ 2	Sufficient material for adequate cytological interpretation
	☐ 3	Sufficient material for limited histological interpretation (core tissue < 500 um at minimal length)
	☐ 4	Sufficient material for low quality histological interpretation (1 core tissue of > 500 um at minimal length)
	☐ 5	Sufficient material for good quality histological interpretation (> 1 core tissue of > 500 um at minimal length)

ID: (새 항목) 기관명: 일련번호: 시험책임자:
Screening 날짜: 대상자: 성별(M/F): 나이:

Inclusion
1) 만 19세 이상 성인
2) 영상 검사에서 췌장에서 기원한 고형 병변이 확인된 경우
3) 위나 십이지장벽을 통한 초음파내시경 유도하 세침 조직 채취가 가능한 경우
4) 임상시험에 참여하여 치료 및 절차를 준수하고, 모든 추적관찰 평가를 위하여 병원을 방문할 의지가 있는 경우
5) 본 임상시험의 목적, 방법 및 효과 등에 대한 설명을 듣고 자발적으로 서면 동의서에 서명한 경우

Exclusion
1) 가임기 여성으로 적절한 피임법을 사용할 수 없거나 임신한 경우 또는 수유 중인 경우
2) 내시경적 시술이 불가능한 경우
3) 출혈성 질환이나 응고장애가 있는 경우 (e.g. DIC)
4) 혈소판 수치(platelet count)가 60,000/mm3 미만 또는 INR 1.5 초과인 경우
5) 불안정한 심장질환이 있거나 임상시험 참여 6개월 이내 심근경색증 (myocardial infarction)으로 진단된 경우
6) 임상시험 참여가 불가능한 정신과적 질환이나 상태인 경우 (e.g. dementia, seizure)
7) 지난 3개월 이내에 다른 의약품 또는 의료기기 임상시험에 참여한 경우
8) 그 외 시험자가 시술이 불가능하다고 판단하는 경우

EUS Date: Operator: Target site:
Approach: Target size (mm): X
Presumptive Diagnosis:

	1st pass	2nd pass
Type of needle:		
Visibility of needle within lesion:		
Needle puncture into the target:		
Easy fo to-and-fro motion:		
Needle angulation after FNB:		
Gross core tissue:		
Pathology result:		
Pathology class:		
Microscopic scoring:	1st Diagnosis	2nd Diagnosis

	Technique	Pathology result
3rd needle pass:		
4th needle pass:		
5th needle pass:		
6th needle pass:		

	Date:	Type:	Management:
Adverse event:			

Final Diagnosis: Based on:

Result

- Study duration: Jul. 2019 ~ Dec. 2019
- 108 patients with pancreatic solid lesions

Variables	N=108
Age, year, median (range)	69 (41~92)
Male:Female	63:45
Site, n (%) Uncinate/head/neck body/tail	 12 (11.1)/37 (34.3)/ 8 (7.4) 28 (25.9)/ 23 (21.3)
Size (mm), mean ± SD	32.1 ± 10.7

Final diagnosis	No. (%)
Benign	
Chronic pancreatitis	1 (0.9)
Autoimmune pancreatitis	2 (1.9)
Schwannoma	1 (0.9)
Ampulla of Vater adenoma	1 (0.9)
Malignancy	
Pancreatic ductal adenocarcinoma	97 (89.8)
Neuroendocrine tumor	4 (3.7)
Metastasis from melanoma	1 (0.9)
Liposarcoma	1 (0.9)

- Adverse events: 8 patients (7.6%)
  - Abdominal pain (3), bleeding (3), fever (1), cerebral infarction (1)

Results – technical evaluation

0	Total			Transgastric approach			Transduodenal approach		
	ClearTip (n=108)	ProCore (n=108)	P value	ClearTip (n=54)	ProCore (n=54)	P value	ClearTip (n=54)	ProCore (n=54)	P value
Easy of puncture									
Easy	100 (92.6%)	100 (92.6%)	1.0	53 (98.1%)	52 (96.3%)	1.0	47 (87.0%)	48 (88.9%)	1.0
Difficult	8 (7.4%)	8 (7.4%)		1 (1.9%)	2 (3.7%)		7 (13.0%)	6 (11.1%)	
Visibility									
Good	107 (99.1%)	100 (92.6%)	0.035	53 (98.1%)	52 (96.3%)	1.0	54 (100%)	48 (88.9%)	0.027
Bad	1 (0.9)	8 (7.4%)		1 (1.9%)	2 (3.7%)			6 (11.1%)	
To-and-fro movement									
Good	100 (92.6%)	101 (93.5%)	1.0	52 (96.3)	52 (96.3%)	1.0	48 (88.9%)	49 (90.7%)	1.0
Bad	8 (7.4%)	7 (6.5%)		2 (3.7%)	2 (3.7%)		6 (11.1%)	5 (9.3%)	
Angulation									
Absent	72 (66.7%)	73 (67.6%)	1.0	48 (88.9%)	48 (88.9%)	1.0	24 (44.4%)	25 (46.3%)	1.0
Present	36 (33.3%)	35 (32.4%)		6 (11.1%)	6 (11.1%)		30 (55.6%)	29 (53.7%)	

Results – cytopathologic evaluation

	Total			Transgastric approach			Transduodenal approach		
	ClearTip (n=108)	ProCore (n=108)	P value	ClearTip (n=54)	ProCore (n=54)	P value	ClearTip (n=54)	ProCore (n=54)	P value
Gross core tissue, n (%)			0.686			0.138			0.761
Presence	66 (61.1)	60 (55.6)		38 (70.0)	31 (57.4)		28 (51.9)	29 (53.7)	
Absence	16 (14.8)	17 (15.7)		10 (18.5)	9 (16.7)		6 (11.1)	8 (14.8)	
Unknown	26 (24.1)	31 (28.7)		6 (11.1)	14 (25.9)		20 (37.0)	17 (31.5)	
Cytologic classification, n (%)			0.608			0.342			0.918
Inadequate	5 (4.6)	8 (7.4)		2 (3.7)	6 (11.1)		3 (5.6)	2 (3.7)	
Benign	14 (13.0)	12 (11.1)		8 (14.8)	8 (14.8)		6 (11.1)	4 (7.4)	
Atypical	13 (12.0)	16 (14.8)		5 (9.3)	6 (11.1)		8 (14.8)	10 (18.5)	
Suspicious for malignancy	27 (25.0)	19 (17.6)		14 (25.9)	7 (13.0)		13 (24.1)	12 (22.2)	
Malignancy	49 (45.4)	53 (49.1)		25 (46.3)	27 (50.0)		24 (44.4)	26 (48.1)	
Microscopic score, n (%)			0.976			0.868			0.822
0	4 (3.7)	6 (5.6)		2 (3.7)	5 (9.3)		2 (3.7)	1 (1.9)	
1	21 (19.4)	19 (17.6)		9 (16.7)	7 (13.0)		12 (22.2)	12 (22.2)	
2	23 (21.3)	22 (20.4)		11 (20.4)	12 (22.2)		12 (22.2)	10 (18.5)	
3	21 (19.4)	24 (22.2)		13 (24.1)	11 (20.4)		8 (14.8)	13 (24.1)	
4	15 (13.9)	15 (13.9)		7 (13.0)	6 (11.1)		8 (14.8)	9 (16.7)	
5	24 (22.2)	22 (20.4)		12 (22.2)	13 (24.1)		12 (22.2)	9 (16.7)	
Microscopic score, n (%)			0.887			1.0			0.840
0-3	69 (63.9)	71 (65.7)		35 (64.8)	35 (64.8)		34 (63.0)	36 (66.7)	
4-5	39 (36.1)	37 (34.3)		19 (35.2)	19 (35.2)		20 (37.0)	18 (33.3)	
Microscopic score, n (%)			1.0			0.423			0.669
0-2	48 (44.4)	47 (43.5)		22 (40.7)	24 (44.4)		26 (48.1)	23 (42.6)	
3-5	60 (55.6)	61 (56.5)		32 (59.3)	30 (55.6)		28 (51.9)	31 (57.4)	
	46.2-64.9	47.1-65.8		46.2-72.4	42.3-68.8		38.5-65.2	44.2-70.6	
Diagnostic accuracy, n (%)	81 (75.0)	76 (70.4)	0.445	41 (75.9)	36 (66.7)	0.288	40 (74.1)	40 (74.1)	1.0
95% CI	66.8-83.2	61.3-79.0		64.5-87.3	54.1-79.2		62.4-85.8	62.4-85.8	

Summary

- Technical evaluation
  - Good visibility in ClearTip
- Cytopathologic evaluation
  - No statistical differences between two needles
- Diagnostic performance
  - Overall diagnostic accuracy: 86.1%
    - 1st pass: 71.3% (77/108)
    - 2nd pass: 74.1% (80/108)
  - No difference between two needles

Conclusion

- New domestic needle (ClearTip)
  - Good technical evaluation
  - No inferiority for the evaluation of pancreatic solid lesions
  - Better diagnostic yield through transduodenal approach

- Further study is needed for non-pancreatic lesions

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