Endoscopic ultrasound guided fine-needle aspiration core biopsy: comparison between an automatic biopsy device and two conventional needle systems

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Summary

Background: *endoscopic ultrasound guided fine-needle aspiration (EUS-FNA) allows cytologic and/or histologic diagnosis of lesions within or adjacent to the gastrointestinal tract. However, the amount of tissue obtained with a regular 22 gauge needle is not always satisfactory. With the development of a needle XNA-10J-KB (Shot-Gun®) that resembles the automatic liver biopsy needle, it is expected that significant samples be obtained more frequently (core biopsy), optimizing histological analysis.* ***Objective:*** *to compare samples obtained with EUS-FNA using 3 different needle systems: GIP®, NA-10J-1® and Shot-Gun®.* ***Methods:*** *19 patients underwent EUS-FNA for diagnosis (5) or tumor staging (14). Mean age was 58.9 years (range 27-82), being 50% men. All patients were submitted to EUS-FNA with the 3 needle models. The Shot-Gun® model was "shot" when its tip was near the target inside the lesion, followed by aspiration. Samples were submitted for cytologic and histologic examination.* ***Results:*** *mean lesion size was 3.0 cm (range 0.8-5.5 cm). Final diagnoses were made after surgery or intra-operative biopsy: 13 pancreatic tumors (12 adenocarcinomas and 1 neuroendocrine tumor), 4 chronic pancreatitis, 1 acute pancreatitis, and 1 cholangiocarcinoma. Specimens adequate for cytologic diagnosis were obtained in 13/19 (68.4%) patients using GIP® model, in 14/19 (73.7%) with NA10J-1® model, and in 17/19 (89.5%) with Shot-Gun, model (p=0.039). Histologic analysis was possible in 10/19 (52.6%) patients using the GIP® model, in 14/19 (73.7%) with NA10J-1®, and in 17/19 (89.5%) with Shot-Gun, model (p=0.005). Adequate samples for cytologic or histologic assessment in 16/19 (84.2%) patients using the GIP® model, in 17/19 (89.5%) with NA10J-1®, and in 18/19 (94.7%) with Shot-Gun, model (p=0.223). In two cases biopsies were negative due to very hard tumors.* ***Conclusion:*** *the Shot-Gun® needle obtained better samples for histological diagnosis than NA10J-1® needle and GIP®.*

Key words: *biopsy, Fine-Needle; Diagnosis; Endosonography; Pancreatic Neoplasms; Endoscopic techniques.*

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Biopsia tecidual con aguja fina guiada por ultrasonido endoscópico: comparación entre un dispositivo automático de la biopsia y dos sistemas de agujas convencionales

Resumen

Introducción: *la ecografía endoscópica asociada a la punción guiada con aguja fina (EUS-FNA) permite el examen citológico y/o diagnóstico histológico de las lesiones dentro o junto al tracto gastrointestinal. Sin embargo, la cantidad de tejido obtenido con una aguja de calibre 22 G no es siempre satisfactoria. Con el desarrollo de una aguja XNA-10J-KB (*Shot-Gun®*) que se asemeja a la biopsia hepática automática como una aguja especial, se espera que se obtemgan muestras importantes con más frecuencia permitindo optimizar el mejor análisis histopatológico.* ***Objetivo:*** *comparar las muestras obtenidas con EUS-FNA con 3 diferentes sistemas de aguja: GIP®, NA-10J-1® y* Shot-Gun®. ***Métodos:*** *19 pacientes fueron sometidos a EUS-FNA para el diagnóstico (5) para el análisis de las etapas del*

tumor (14). La edad media fue de 58,9 años (rango 27-82), siendo el 50% hombres. Todos los pacientes fueron sometidos a EUS-FNA con los 3 modelos de aguja. Del Shot-Gun® fue "disparada" su punta cuando estaba cerca de la meta en el interior de la lesión, seguida de aspiración. Las muestras se sometieron a examen citológico e histológico. ***Resultados:*** *el promedio de tamaño de la lesión fue de 3,0 cm (rango 0,8-5,5 cm). Los diagnósticos definitivos fueron hechos después de la cirugía o la biopsia intra-operatoria: 13 tumores de páncreas (12 adenocarcinomas y 1 tumor neuroendócrino), 4 de pancreatitis crónica, 1 de pancreatitis aguda, y 1 de colangiocarcinoma. Las muestras adecuadas para el diagnóstico citológico se obtuvieron en 13/19 (68,4%) pacientes que utilizan GIP®, en 14/19 (73,7%) con NA10J-1®, y en 17/19 (89,5%) con* Shot-Gun® *(p = 0,039). El análisis histológico fue posible en 10/19 (52,6%) pacientes que utilizan el GIP®, en 14/19 (73,7%) con NA10J-1®, y en 17/19 (89,5%) con* Shot-Gun® *(p = 0,005). Suficientes muestras para citológico o histológico de evaluación en 16/19 (84,2%) pacientes que utilizan el modelo GIP®, en 17/19 (89,5%) con NA10J-1®, y en 18/19 (94,7%) con* Shot-Gun® *(p = 0,223). En dos casos las biopsias fueron negativos debido a tumores muy duros.* ***Conclusión:*** *la aguja* Shot-Gun® *ha obtenido mejores muestras para diagnóstico histológico que NA10J-1® aguja y GIP®.*

Palabras claves: *biopsia, aguja fina; diagnóstico; endosonografía; neoplasias de páncreas; técnicas endoscópicas.*

Endoscopic ultrasound guided fine-needle aspiration (EUS-FNA) is a method that allows histological diagnosis of lesions within or adjacent to the gastrointestinal tract. However, only a few studies comparing EUS-FNA needle models has been published.[6,31]

Fritscher-Ravens et al,[6] studied the performance of two needle models in 30 focal pancreatic lesions. No statistically significant differences were detected between both needle assemblies. No complications were reported using GIP® model. However, Wilson-Cook model provided samples with adequate cellularity more often.[21]

Aspirates from 22-23 gauge needles usually provide adequate material for cytologic examination. On the other hand, 18-19 gauge needles are also prone to obtain material for histological diagnosis. However, EUS-FNA with this thick needles are somewhat cumbersome specially in indurated pancreatic tumors.[1,6,7]

Recently spring-coil loaded models that allow the needle to be "shot" into the mass (similar to the mechanism used for liver biopsy) have been developed. Binmoeller et al[5] evaluated a prototype automated spring-loaded needle in four indurated pancreatic lesions in which EUS-FNA with conventional needles has failed. The new model provided a core specimen for histological and cytologic diagnosis in all cases with no complications.

A pancreatic core biopsy would be advantageous in evaluating patients with pancreatic lesions in order to make a definitive diagnosis. The aim of this study was to compare diagnostic performance of 2 similar needle systems (GIP® and NA-10J-1®) and XNA-10J-KB Shot-Gun®.

Patients and Methods

During six months, 46 consecutive patients underwent EUS-FNA for diagnosis or tumor staging. Of these, 23 underwent biopsies using 3 different needle models at the same session. Four patients were excluded because final diagnosis could not be confirmed by surgery or intra-operative biopsy.

Patients were selected to undergo EUS-FNA on the basis of their clinical history and evidence of a pancreatic mass lesion on endosonographic evaluation using a Pentax FG 36-UX sectorial echoendoscope (Pentax Precision Instruments Corp., Orangeburg, New York) and a Hitachi EUB 405 ultrasound unit (Mitsubishi, Conshockon, Philadelphia). This technique was performed to confirm diagnosis in 5 patients (26.3%) and staging in 14 patients (73.7 %) with pancreatic masses (8 women, 11 men).

Mean age was 57.8 ± 15.3 years (mean ± SD, range 27 to 82 years). In all cases EUS-FNA was important for patient management, confirming or changing clinical/surgical strategies.

EUS-FNA was performed in an outpatient's basis and patients were kept under observation for 2 hours after the procedure. Prophylactic antibiotics were not routinely given. All patients underwent surgery after the biopsies. In twelve lesions located in the pancreatic head region, specimens were obtained by puncturing through duodenum. For those located in the pancreatic body EUS-FNA were performed from the stomach.

Needles

In this study, the authors used 145 cm long 22 gauge EUS-FNA models: GIP® model (Medizintechnik GMBH, Grassau/Germany) and NA-10J-1® model (Olympus Optical Co., Melville, New York). The needle penetration depth is 6 cm and 6,5 cm, respectively (Figures 1 e 2).

The Shot-Gun®/XNA-10J-KB (Olympus Co., Melville, New York) model is 169.6 cm long, with a 0.7-mm outer diameter (Figure 3). With this model, the authors used NA-10J-1® needle. A blunt-tipped stylet was passed through the lumen of the needle and Luer-locked into the needle hub. The stylet protruded 2 mm beyond the tip of the needle. A 139.2 cm long spiral metal sheath was screwed into the distal end of the handle.

Figure 1. *This picture shows a 22 gauge EUS-FNA GIP® model (Medizintechnik GMBH, Grassau/Germany). The needle penetration depth is 6 cm.*

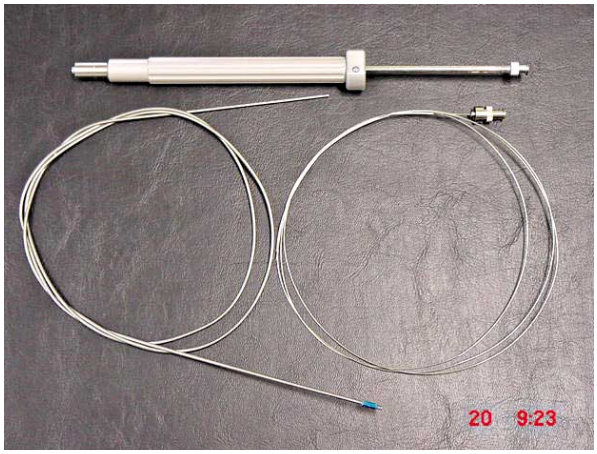


Figure 2. *NA-10J-1® model (Olympus Optical Co., Melville, New York). The needle penetration depth is 6,5 cm.*

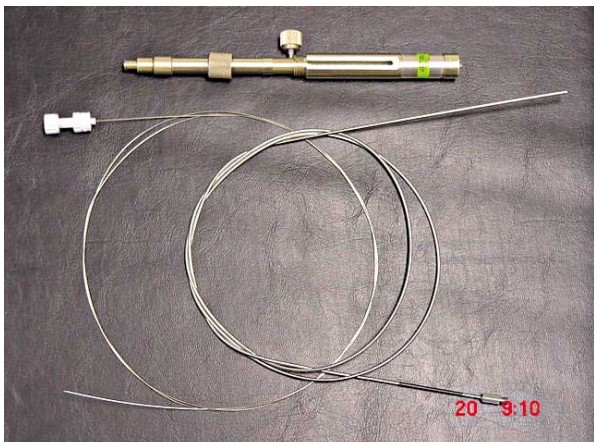
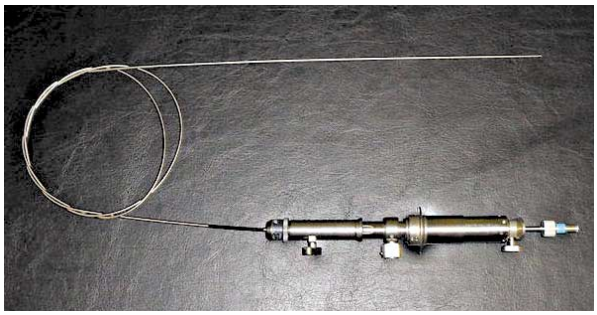


Figure 3. *The Shot-Gun®/XNA-10J-KB (Olympus Co., Melville, New York) model.*



The stainless-steel trigger handle consisted of the following components: piston, piston inlet port, piston screw-lock, spring coil, main cylinder, spring-loading unit, trigger button, cylinder sleeve screw-lock, calibrating sleeve, Luer-lock attachment to the echoendoscope.

The needle was manually advanced and withdrawn by moving the piston within the main cylinder. The spring mechanism was activated by pulling back on the spring-loading unit until a "click" was appreciated. Penetration depth of the needle was set up to a maximum of 30 mm using the calibrating sleeve. The spring mechanism was released by pressing the trigger button. The length of the spiral metal sheath was adjusted using the cylinder sleeve, which was fixed using the screw lock.

Procedure

EUS-FNA was performed using three different needle models: GIP®, NA-10J-1® and Shot-Gun®.

Each needle was inserted once in each lesion. The same sequence (GIP®, NA-10J-1® and XNA-10J-KB®) was used in every case. Once lesion was penetrated the stylet was advanced to original position to "unplug" needle (GIP® and NA-10J-1®). Stylet was removed and suction was applied using a 20 ml syringe while moving needle to and fro within lesion. Before removing needle, suction was released by disconnecting the syringe.

A different technique was applied for Shot-Gun® model:

A) Stylet was withdrawn 1 cm,
B) Gastrointestinal wall was punctured and needle tip was positioned at the periphery of the lesion,
C) Stylet was fully advanced to unplug the needle,
D) Distance between the needle tip and the desired point of puncture in the lesion was measured,

E) The needle penetration depth was set,
F) Stylet was removed from the needle,
G) Suction was applied using a 20 ml syringe,
H) The spring mechanism was released (under endosonographic control of needle movement),
I) The endoscopist moved the needle to and from within the lesion,
J) The syringe was detached,
K) The needle and the handle were removed.

After the needle pass, the aspirates were ejected from the needle. Core biopsy specimens were fixed in formaldehyde and aspirates were smeared onto glass slides and fixed in 98% ethanol. Pathologists were unaware of needle system used. They were not present during the procedure.

Pathological findings

All samples were analyzed by two pathologists (FV and GCS), which reached an agreement on the diagnosis. They considered appropriate when the samples were found large quantity of cellular elements that allow obtaining a diagnosis or in the case of obtaining tissue sample by the presence of microfragments. The immunohistochemistry was performed only when the pathologists believed its use was necessary only in case number 14 in this series.

Statistical analysis

For continuous parameters, results were expressed as mean ± SD. Categorical data were expressed using absolute frequencies and percentages. Statistical analysis was performed using GraphPad InStat version 3.00 for Windows 95, GraphPad Software, San Diego California USA, www.graphpad.com, and SPSS for Windows version 11.0.0, SPSS Inc., Chicago Illinois USA. Cochran's Q test was used to test for adequacy of cytologic/histologic specimens. Sensitivity, specificity, negative and positive predictive values were calculated with 95% confidence limits. Values of $p \leq 0.05$ were considered significant.

For the purpose of statistical analysis, samples with insufficient material and negative for malignancy were classified as negative, while specimens with atypical cells were grouped with positive for malignancy samples as positive.

This study is in accordance with the World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects and was approved by the Ethical Review Committee of our University. Informed consent was obtained from all patients.

Results

Mean lesion size was 3.0 ± 1.3 cm (range 0.8 to 5.5 cm). Final diagnoses, made after surgery or intra-operative biopsy were: 13 (68.4 %) pancreatic tumors (12 ductal adenocarcinomas and 1 neuroendocrine tumor), 4 (21.0 %) chronic pancreatitis, 1 (5.3 %) acute pancreatitis, and 1 (5.3 %) cholangiocarcinoma (Table 1).

Specimens adequate for cytologic diagnosis were obtained in 13/19 (68.4%) patients using GIP® model, in 14/19 (73.7%) with NA10J-1® model, and in 17/19 (89.5%) with Shot-Gun, model (p=0.039). In 10 cases (52.6%), all models studied provided adequate samples (table 2).

Histologic analysis was possible in 10/19 (52.6%) patients using the GIP® model, in 14/19 (73.7%) with NA10J-1®, and in 17/19 (89.5%) with Shot-Gun, model (p=0,005). In 9 cases (47.4%), all models studied provided adequate samples.

Adequate samples for cytologic or histologic assessment in 16/19 (84.2%) patients using the GIP® model, in 17/19 (89.5%) with NA10J-1®, and in 18/19 (94.7%) with Shot-Gun, model (p=0.223). In 16 cases (84.2%), all models studied provided adequate samples.

Results of cytologic examination in malignancy detection with the needle models studied are shown in tables 3 (including all subjects) and 4 (excluding inadequate material cases).

Results of histologic examination in malignancy detection with the needle models studied are given in tables 5 (including all subjects) and 6 (excluding inadequate material cases).

Then we examined results of combined cytologic/histologic examination in malignancy detection with the needle models studied (tables 7 - including all subjects and 8 - excluding inadequate material cases).

Results of combined EUS – FNA needle models cytologic, histologic, and combined examination in malignancy detection are presented in tables 9 (including all subjects) and 10 (excluding inadequate material cases).

In two cases of indurated pancreatic masses, cytologic examination of samples obtained by GIP® and NA-10J-1® systems were suspicious of malignancy and positive by Shot-Gun®.

Table 1. *Characteristics of patients who underwent EUS-FNA with 3 needle models.*

Patient	Age (yr)	Gender	Lesion Type	Site	Size (cm)	Final diagnosis
1	65	M	Pancreatic tumor	head	5.5	Adenocarcinoma
2	42	M	Pancreatic tumor	head	3.0	Adenocarcinoma
3	27	F	Peri-pancreatic	Biliary tree	5.4	Cholangiocarcinoma
4	63	F	Pancreatic tumor	head	3.1	Adenocarcinoma
5	68	F	Pancreatic tumor	head	2.9	Adenocarcinoma
6	35	M	Pancreatic tumor	body	3.5	Adenocarcinoma
7	65	F	Pancreatic tumor	head	2.7	Adenocarcinoma
8	75	M	Pancreatic tumor	head	4.2	Adenocarcinoma
9	56	F	Pancreatic tumor	head	2.9	Adenocarcinoma
10	57	F	Pancreatic tumor	head	3.5	Adenocarcinoma
11	68	M	Pancreatic tumor	head	3.4	Adenocarcinoma
12	53	M	Pancreatic tumor	head	1.8	Adenocarcinoma
13	82	M	Pancreatic tumor	head	3.2	Adenocarcinoma
14	64	F	Pancreatic tumor	body	2.5	Neuroendocrine Tumor
15	76	M	Pancreatic tumor	head	0.8	Chronic pancreatitis
16	47	M	Pancreatic tumor	head	2.2	Chronic pancreatitis
17	45	M	Pancreatic tumor	head	3.2	Chronic pancreatitis
18	38	M	Pancreatic tumor	body	1.2	Acute pancreatitis
19	72	F	Pancreatic tumor	body	1.2	Chronic pancreatitis

M=male, F=female

Table 2. *EUS-FNA results for each needle used in this subject.*

	GIP®		NA-10J-1®		SHOT GUN	
Patient	Cytology	Histology	Cytology	Histology	Cytology	Histology
1	Normal cells	Inadequate	Normal cells	Cellular atypia	Normal cells	Adenocarcinoma
2	Inadequate	Inadequate	Inadequate	Inadequate	Inadequate	Inadequate
3	Normal cells	Inadequate	Inadequate	Normal cells	Normal cells	Adenocarcinoma
4	Malignant	Adenocarcinoma	Malignant	Adenocarcinoma	Malignant	Adenocarcinoma
5	Malignant	Adenocarcinoma	Malignant	Adenocarcinoma	Malignant	Adenocarcinoma
6	Inadequate	Normal cells	Malignant	Adenocarcinoma	Malignant	Adenocarcinoma
7	Malignant	Inadequate	Malignant	Inadequate	Inadequate	Adenocarcinoma
8	Inadequate	Inadequate	Inadequate	Inadequate	Normal cells	Adenocarcinoma
9	Normal cells	Inadequate	Normal cells	Adenocarcinoma	Normal cells	Adenocarcinoma
10	Normal cells	Normal cells	Normal cells	Inadequate	Normal cells	Adenocarcinoma
11	Normal cells	Adenocarcinoma	Cellular atypia	Adenocarcinoma	Cellular atypia	Adenocarcinoma
12	Malignant	Inadequate	Malignant	Inadequate	Normal cells	Inadequate
13	Malignant	Normal cells	Malignant	Cellular atypia	Cellular atypia	Normal cells
14	Inadequate	Normal cells	Inadequate	Normal cells	Normal cells	Neuroendocrine
15	Inadequate	Normal cells	Normal cells	Normal cells	Normal cells	Acinar atrophy
16	Normal cells	Inflamatory	Inflamatory	Inflamatory	Inflamatory	Acinar atrophy
17	Inadequate	Inadequate	Inflamatory	Normal cells	Inflamatory	Inflamatory
18	Normal cells	Normal cells	Inflamatory	Inflamatory	Normal cells	Inflamatory
19	Inflamatory	Inadequate	Inadequate	Inflamatory	Inflamatory	Inflammatory

Table 3. *EUS-FNA cytologic examination results of each needle model in malignancy detection.*

	GIP®	NA-10J-1®	SHOT GUN
Sensitivity*	38.5% (13.8%-68.4%)	50.0% (23.0%-77.0%)	50.0% (18.7%-81.3%)
Specificity*	100% (54.1%-100%)	100% (47.8%-100%)	100% (66.4%-100%)
Positive Predictive Value*	100% (47.8%-100%)	100% (59.0%-100%)	100% (47.8%-100%)
Negative Predictive Value*	42.9% (17.7%-71.1%)	41.7% (15.2%-72.3%)	64.3% (35.1%-87.2%)

*%(95%CI)

Table 4. *EUS-FNA cytologic examination results for each needle model in malignancy detection (excluding inadequate material cases).*

	GIP®	NA-10J-1®	SHOT GUN
Sensitivity*	50.0% (18.7%-81.2%)	70.0% (34.8%-93.3%)	41.7% (15.7%-72.3%)
Specificity*	100% (29.2%-100%)	100% (39.8%-100%)	100% (47.8%-100%)
Positive Predictive Value*	100% (47.8%-100%)	100% (59.0%-100%)	100% (47.8%-100%)
Negative Predictive Value*	37.5% (8.5%-75.5%)	57.1% (18.4%-90.1%)	41.7% (15.2%-72.3%)

*%(95%CI)

Table 5. *EUS-FNA cytologic examination results for each needle model in malignancy detection (excluding inadequate material cases).*

	GIP®	NA-10J-1®	SHOT GUN
Sensitivity*	21.4% (4.6%-50.8%)	50.0% (23.0%-77.0%)	78.6% (49.2%-95.3%)
Specificity*	100% (47.8%-100%)	100% (47.8%-100%)	100% (47.8%-100%)
Positive Predictive Value*	100% (29.2%-100%)	100% (59.0%-100%)	100% (71.5%-100%)
Negative Predictive Value*	31.2% (11.0%-58.7%)	41.7% (15.2%-72.3%)	62.5% (24.5%-91.5%)

*%(95%CI)

Table 6. *EUS-FNA histologic examination results for each needle model in malignancy detection (excluding inadequate material cases).*

	GIP®	NA-10J-1®	SHOT GUN
Sensitivity*	42.9% (9.9%-81.6%)	77.8% (40.0%-97.2%)	91.7% (61.5%-99.8%)
Specificity*	100% (29.2%-100%)	100% (47.8%-100%)	100% (47.8%-100%)
Positive Predictive Value*	100% (29.2%-100%)	100% (59.0%-100%)	100% (71.5%-100%)
Negative Predictive Value*	42.9% (9.9%-81.6%)	71.4% (29.1%-96.3%)	83.3% (35.9%-99.6%)

*%(95%CI)

Table 7. *EUS-FNA combined cytologic/histologic examination results for each needle model in malignancy detection.*

	GIP®	NA-10J-1®	SHOT GUN
Sensitivity*	42.9% (17.7%-71.1%)	64.3% (35.1%-87.2%)	85.7% (57.2%-98.2%)
Specificity*	100% (47.8%-100%)	100% (47.8%-100%)	100% (47.8%-100%)
Positive Predictive Value*	100% (54.1%-100%)	100% (66.4%-100%)	100% (73.5%-100%)
Negative Predictive Value*	38.5% (13.9%-68.4%)	50.0% (18.7%-81.3%)	71.4% (29.1%-96.3%)

*%(95%CI)

Table 8. *EUS-FNA combined cytologic/histologic examination results for each needle model in malignancy detection (excluding inadequate material cases).*

	GIP®	NA-10J-1®	SHOT GUN
Sensitivity*	50.0% (21.1%-78.9%)	75.0% (42.8%-94.5%)	92.3% (64.0%-99.8%)
Specificity*	100% (39.8%-100%)	100% (47.8%-100%)	100% (47.8%-100%)
Positive Predictive Value*	100% (54.1%-100%)	100% (66.4%-100%)	100% (73.5%-100%)
Negative Predictive Value*	40.0% (12.2%-73.8%)	62.5% (24.5%-91.5%)	83.3% (35.9%-99.6%)

*%(95%CI)

Table 9. *EUS-FNA all models combined cytologic, histologic, and combined examination results for each needle model in malignancy detection.*

	CYTOLOGIC EXAMINATION	HISTOLOGIC EXAMINATION	COMBINED
Sensitivity*	57.1% (28.9%-82.3%)	85.7% (57.2%-98.2%)	92.9% (66.1%-99.8%)
Specificity*	100% (47.8%-100%)	100% (47.8%-100%)	100% (47.8%-100%)
Positive Predictive Value*	100% (63.1%-100%)	100% (73.5%-100%)	100% (75.3%-100%)
Negative Predictive Value*	45.4% (16.7%-76.6%)	71.4% (29.1%-96.3%)	83.3% (35.9%-99.6%)

*%(95%CI)

Table 10. *EUS-FNA all models combined cytologic, histologic, and combined examination results for each needle model in malignancy detection (excluding inadequate material cases).*

	CYTOLOGIC EXAMINATION	HISTOLOGIC EXAMINATION	COMBINED
Sensitivity*	53.8% (25.1%-80.8%)	100% (73.5%-100%)	100% (75.3%-100%)
Specificity*	100% (47.8%-100%)	100% (47.8%-100%)	100% (47.8%-100%)
Positive Predictive Value*	100% (59.0%-100%)	100% (73.5%-100%)	100% (73.5%-100%)
Negative Predictive Value*	45.4% (16.7%-76.6%)	100% (47.8%-100%)	100% (47.8%-100%)

*%(95%CI)

Complications

There were 2 (12.5%) complications after the procedures. One (6.25%) patient had mild, self limited bleeding and another one (6.25%) had mild abdominal pain. Both patients were treated conservatively.

Discussion

Histologic confirmation of pancreatic mass lesions has a fundamental role in therapeutic decision, since different diseases may be indistinguishable by available imaging methods. Chemotherapy and radiation therapy protocols usually require diagnostic confirmation by histological studies.[3]

EUS-FNA accuracy is superior to CT or US guided FNA accuracies, particularly in the case of small lesions.[3,6,9,21,27,28] EUS-FNA is unique since it can be performed at the same occasion of the lesion detection and staging.[29]

In this series, EUS-FNA had sensitivity of 92.9%, specificity of 100%, positive predictive value of 100%, and negative predictive value of 83.3% in malignancy detection. In the literature, EUS-FNA malignancy detection sensitivity varies from 59% to 94%, specificity from 71% to 100%, positive pre-

dictive value from 96% to 100%, negative predictive value from 16% to 86%, and accuracy in pancreatic mass lesions varies from 65% to 92%.[4,8,10,18,20,25,27,33,36,39-42]

Cytodiagnosis of pancreatic carcinomas is difficult in part due to the scirrhous nature of these tumors, in which a few malignant cells may be surrounded by large amounts of fibrosis, necrosis and inflammatory cells. They may present as indurated mass lesions, which make EUS-FNA impossible in up to 15% of the procedures.[3,6,7,10,18,21,25,28,40,42] Recently spring-coil loaded models that allow the needle to be "shot" inside the mass (similar to the system used for liver biopsy) have been developed. Binmoeller et al evaluated a prototype automated spring-loaded needle in four indurated pancreatic lesions in which EUS-FNA with conventional needles has failed. The new model provided a core specimen for histologic and cytologic diagnosis in all cases with no complications.[5]

Aspirates from 22-23 gauge needles sometimes provide adequate material for histological diagnosis.[9,23] Large caliber needles could improve adequacy of aspirates for histologic study. Binmoeller, et al, using a 18 Gauge prototype needle model, were able to obtain adequate samples for histological analysis in 31/45 (68%) pancreatic lesions, with a complication rate of 1/45 (2,3%).[7] In our series, Shot-Gun® achieved the best result and provided tissue samples in 17/19 (89.5%) cases.

In this study, broad overlaps of confidence intervals between EUS-FNA results of different needle models in malignancy detection preclude a conclusion about which one would achieve the best results.

During EUS-FNA several needle passes are usually performed (at least three passes associated with several to and from needle movements inside the mass).[1,4,7,8,10-15,21,24-28,32,35,38,42] The presence of a cytopathologist or cytology technician during the procedure is important to assess specimen adequacy and to decide the use of special staining methods or cultures.[7,10,11,13,14,16,26,27,30,35,37,38,42]

We only performed one needle pass per model in each lesion. Cytopathologist or cytology technician were not present during our procedures. Finally, we defined specimen adequacy by observation of pancreatic acinar cells in the sample. All these methodologic issues may have contributed to differences observed between our results and the literature. On the other hand, a bigger sample size would be able to narrow confidence intervals observed in this study.

Diagnosis of pancreatic carcinoma is usually defined by combination of follow up and histologic diagnosis. In our study, final diagnosis was established by surgical biopsy in all cases. It is obvious that tissue diagnosis is the ideal gold-standard for pancreatic carcinoma studies. However, we also know that studies like ours would be difficult to perform with larger samples. On the other hand, diagnostic accuracy may be similar in histologic proven and follow-up based diagnosis groups.[27]

EUS-FNA with conventional needle models of indurated pancreatic masses is problematic because when needle encounters resistance to advancement, pushing away the tip of echoendoscope, real time EUS monitoring is lost. In our series, an accessory channel damage occurred during a procedure with a GIP® model.

"Core biopsy" may be advantageous because provides more information than cytologic diagnosis: histological origin, tumor differentiation, presence of inflammation, and fibrosis. In 7 cases of malignant disease (1 neuroendocrine tumor, 1 cholangiocarcinoma, and 5 ductal adenocarcinomas), in which cytologic assessment were negative, diagnostic confirmation was possible by tissue diagnosis: none with GIP® model, 2 with NA-10J-1® model, and 6 with Shot-Gun, model.

In just 1 case EUS-FNA were not able to provide adequate samples for both cytological and histological studies. In one case malignant cells were detected by both methods.

Spring loaded needle models is an attractive approach to obtain adequate samples for cytologic and histologic diagnosis and EUS-FNA of indurated pancreatic masses. In our experience, EUS-FNA with thicker needles seems to be somewhat more difficult than with spring loaded devices.

EUS-FNA of pancreatic mass lesions is safe, with complication rates varying from 0 to 5%. Major complications are bleeding, infection, perforation, and pancreatitis.[1-4,7,10-15,17-23,25,27,28,34,36,40-42] In our series, minor complications occurred in two cases (12.5%): self limited bleeding and abdominal pain. Both cases were treated conservatively. There were no acute pancreatitis.

In conclusion, core specimens for histologic examination can be safely obtained using Shot-Gun® model in conjunction with the Pentax convex array echoendoscope. Histology and cytology should be

regarded as complementary for final diagnosis. Core biopsy provided more tissue-specific information. Shot-Gun® prototype obtained better tissue samples for histological study, improving quality of the final diagnosis. Further studies are required to determine the best strategy to maximize EUS-FNA diagnostic yield and sensitivity.

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