

Clinical Literature Summary for the:

**Infinity[®] ERCP
sampling device**



Endoscopy

Infinity ERCP sampling device - Collecting Quality Samples During ERCP

The Infinity ERCP sampling device is purpose built for collecting substantial and quality samples from strictures in the biliary duct.

The Infinity device features...

compatible with long and short guidewires

stiffer bristles to help create a defect in the tissue

softer bristles to capture abraded material

spaces between the bristles to help pack cells into the catheter



Detachable handle with
"Salvage Cytology" capability

radio-opaque marker to identify
brush location under flouroscopy

Indications for Use:

The Infinity ERCP sampling device is intended to be used to retrieve cytological cell samples in the gastrointestinal tract.

*Brushing with Infinity ERCP sampling device allowed for the diagnosis of malignancy and the type of cancer in **85% of the cases.***¹

- Barrioz et al., 2014

Agreement Between Endoscopic Ultrasound-Guided Fine-Needle Aspiration and Endobiliary Brush Cytology in Suspected Pancreaticobiliary Malignancies

Matthew J. Sullivan, Hope Kincaid, Shashin Shah, Hiral N. Shah, 2017²

Device	Patients	Sample Adequacy	Sensitivity
Infinity ERCP sampling device	n=41	97.6%	84.0%
EUS-FNA*	n=41	80.5%	80.8%

Study Details

- **Purpose:** Investigate whether Infinity ERCP sampling device's brush design would provide more adequate samples and have high agreement with EUS-FNA in patients who underwent both procedures.
- **Background:** A retrospective chart review was conducted of all patients who underwent both EUS-FNA and endobiliary brush cytology for suspicion of pancreaticobiliary malignancy from January 2013 to May 2015.
- **Method (Brushing Technique):**
 - » Strictures were brushed using a minimum of seven up-and-down motions before removing the brush and catheter.
 - » Obtained cells were collected in cytology solution along with the brush head.
 - » The catheter was then flushed into the same solution and submitted for interpretation by a group of in-house multidisciplinary pathologists with gastroenterology experience.
- **Results:**

	Infinity ERCP sampling device		EUS-FNA	
	Atypical Negative	Atypical Positive	Atypical Negative	Atypical Positive
Sensitivity, % (95 %CI)	60.0 (38.7 - 78.9)	84.0 (63.9 - 95.5)	69.2 (48.2 - 85.7)	80.8 (90.7 - 93.5)
Specificity, % (95 %CI)	93.3 (68.1 - 99.8)	66.7 (38.4 - 88.2)	100 (71.5 - 100)	81.8 (48.2 - 97.7)
PPV, % (95 %CI)	93.8 (69.8 - 99.8)	80.8 (60.7 - 93.5)	100 (81.5 - 100)	91.3 (72.0 - 98.9)
NPV, % (95 %CI)	58.3 (36.6 - 77.9)	71.4 (41.9 - 91.6)	57.9 (33.5 - 79.8)	64.3 (35.1 - 87.2)
Cancer detection rate	57.7%	80.8%	69.2%	80.8%

PPV, positive predictive value; NPV, negative predictive value; CI, confidence interval. **There was one inadequate brush cytology sample and four inadequate EUS-FNA samples. Therefore, calculations were performed using 40 samples for brush cytology and 37 for EUS-FNA.**

- » There was only a moderate level of agreement between EUS-FNA and biliary cytology samples (Cohen's Kappa; $k = 0.42$, $P = 0.0001$).
- » In three cases – two pancreatic adenocarcinomas and one cholangiocarcinoma – **the Infinity device diagnosed malignancy and EUS-FNA was either negative for malignancy or provided atypical cellularity.**
- » **If brush cytology was not performed, these malignancies may have been missed or additional diagnostic procedures at increased cost and risk of morbidity would have been required.**

Conclusion

*"In conclusion, we found that the **Infinity ERCP sampling device resulted in increased sample adequacy** compared with historical rates of brush cytology; this correlates with previous studies of this brush."*

"If the Infinity ERCP sampling device truly increases sample adequacy it could potentially provide results comparable to EUS-FNA at a lower cost."

Improved Endoscopic Retrograde Cholangiopancreatography Brush Increases Diagnostic Yield of Malignant Biliary Strictures

Frederick K Shieh, Adelina Luong-Player, Harshit S Khara, Haiyan Liu, Fan Lin, Matthew J Shellenberger, Amitpal S Johal, David L Diehl, 2014³

Device	Patients	Sample Adequacy	Sensitivity
Infinity ERCP sampling device	n=32	n/a	78.1%
Standard wire-guided brush	n=46	n/a	37.0%

Study Details

- **Purpose:** To determine if a new brush design could improve the diagnostic yield of biliary stricture brushings.
- **Background:**
 - » Retrospective chart review was performed of all endoscopic retrograde cholangiopancreatography procedures with malignant biliary stricture brushing between January 2008 and October 2012.
 - » A standard wire-guided cytology brush was used prior to protocol implementation in July 2011, after which, a new Infinity ERCP sampling device (9FR) was used for all cases.
- **Method:**

Historical Control:

 - » Cytology brushing was performed with a standard 8FR wire-guided brush (Cook Medical's Cytomax or Boston Scientific's RX Brush).
 - » 2 passes across the stricture were done.
 - » Smear on slides were prepared, the brush head was then cut off and sent in the cytology transport medium (RPML).

New Standardized Protocol:

 - » All cases were done with Infinity ERCP sampling device and 2 passes were always made of the stricture.
 - » 2 smears were prepared on the first pass (one air dried and one fixed), and the brush agitated in RPML to dislodge cells. The brush was rinsed with water. On the second pass, the brush was cut off into the RPML.
 - » Salvage cytology was also done by injecting 5mL of RPML through the brush catheter after brushing was completed. The 2 slides and the tube of the RPML were submitted, and a cell block made.
- **Results:**
 - » All specimens were reviewed by blinded pathologists who determined whether the sample was positive or negative for malignancy.

	Infinity ERCP sampling device	Standard Wire-Guided Brush
Pancreatic adenocarcinoma	17/23 (73.9%)	6/20 (30.0%)
Cholangiocarcinoma	7/7 (100%)	8/22 (36.4%)
Other malignancies	1/2 (50.0%) 2 Gallbladder	3/4 (75.0%) 2 Gallbladder, 1 Colorectal, 1 Unknown Primary

Conclusion

There was an increased diagnostic yield of brush cytology of these malignant biliary strictures in the new protocol group as compared to the historical controls ($P = 0.0003$).

*"The use of a **new brush design for brush cytology of biliary strictures shows increased diagnostic accuracy**, likely due to improved cellular yield, as evidenced by an increase in number of cellular clusters obtained."*

Prospective, Randomized, Single-Blinded Controlled Trial of Infinity Cytology Brush vs. Standard Cytology Brush for Diagnosis of Biliary Stricture: An Interim Analysis

Nirav C. Thosani, Subhas Banerjee, Ann M. Chen, Shai Friedland 2014⁴

Device	Patients	Sample Adequacy	Sensitivity
Infinity ERCP sampling device	n=17	100%	86.7%
Standard wire-guided brush	n=20	70.0%	60.0%

Study Details

- **Purpose:** Determine the accuracy of Infinity ERCP sampling device (ICB) vs. standard cytology brush in diagnosis of biliary stricture in randomized blinded controlled trial.
- **Background:**
 - » Patients are randomized to either brush using computerized random sequence generation in concealed envelopes.
 - » Both groups were similar in regard to basic demographics, stricture location and final diagnosis (benign vs. malignant).
 - » All patients underwent dilation of the stricture prior to brushing per protocol.
- **Method:**
 - » Brushing was done in standard fashion.
 - » Pathologists are blinded to the type of brush and rate each brushing sample for adequate cellularity.
 - » Accurate diagnosis is defined as brushing sample with (1) sufficient cellularity as per Camps grading method and (2) suspicious or diagnostic for malignancy in patients with cancer & normal or atypical in patients without cancer, as determined based on diagnostic interventions and clinical follow up.
- **Results:**

	Infinity ERCP sampling device	Standard Wire-Guided Brush
Malignant Strictures Accuracy	75.0%	50.0%
Benign Strictures Accuracy	100%	66.7%

Conclusion

*"In our interim analysis, we found fewer insufficient samples and **most samples with adequate cellularity with ICB and a trend towards higher diagnostic accuracy with Infinity ERCP sampling device.**"*

The Infinity Brush Improves the Results of Brush Cytology of Malignant Biliary Strictures

Thierry Barrioz, M. Wangermez, P. Levillain, M. Beauchant, 2014 ¹

Device	Patients	Sample Adequacy	Sensitivity
Infinity ERCP sampling device	n=20	n/a	85.0%
Standard wire-guided brush	n=20	n/a	30.0%

Study Details

- **Purpose:** Evaluate, in a prospective randomized controlled study, the efficacy of the Infinity ERCP sampling device.
 - **Background & Methods:**
 - » From May to July 2012, patients with suspected malignant biliary stenosis underwent endoscopic retrograde cholangiography with brushing.
 - » Brushing was performed with either an Infinity brush or a Standard wire-guided brush.
 - » 2 passes were made each device.
- Sample Processing Technique:
- » A smear was prepared from the sample.
 - » The brush was then placed into a tube of formalin and subjected to centrifugation.
 - » The resulting pellet was immersed in paraffin wax.
 - » The smear and cell block were then submitted to the pathology lab.
 - » The confirmation of the malignant nature of the stenosis and histological types that were collected by brushing were confirmed either by EUS punctures or biopsies per cholangioscopy.

- **Results:**

	Infinity ERCP sampling device	Standard Wire-Guided Brush
Location of stricture		
Proximal bile duct	10	9
Distal bile duct	8	9
Left hepatic duct	1	2
Secondary branch IHD	1	0
Suggested Diagnosis		
Cholangiocarcinoma CBD	13	11
Pancreatic cephalic cancer	7	9
Positive Diagnosis	85.0%	30.0%

Conclusion

*“The new Infinity brush significantly **improves the results of brush cytology of biliary strictures**. The quality of the sample not only confirmed malignancy but in most cases the type of histology of the lesion as well.”*

ERCP - Sampling of Malignant Biliary Strictures

David L. Diehl, 2012⁵

Procedures

ERCP (endoscopic retrograde cholangiopancreatography) performed for biliary obstruction.

A total of 36 procedures were performed on strictures of suspected cancerous origin:

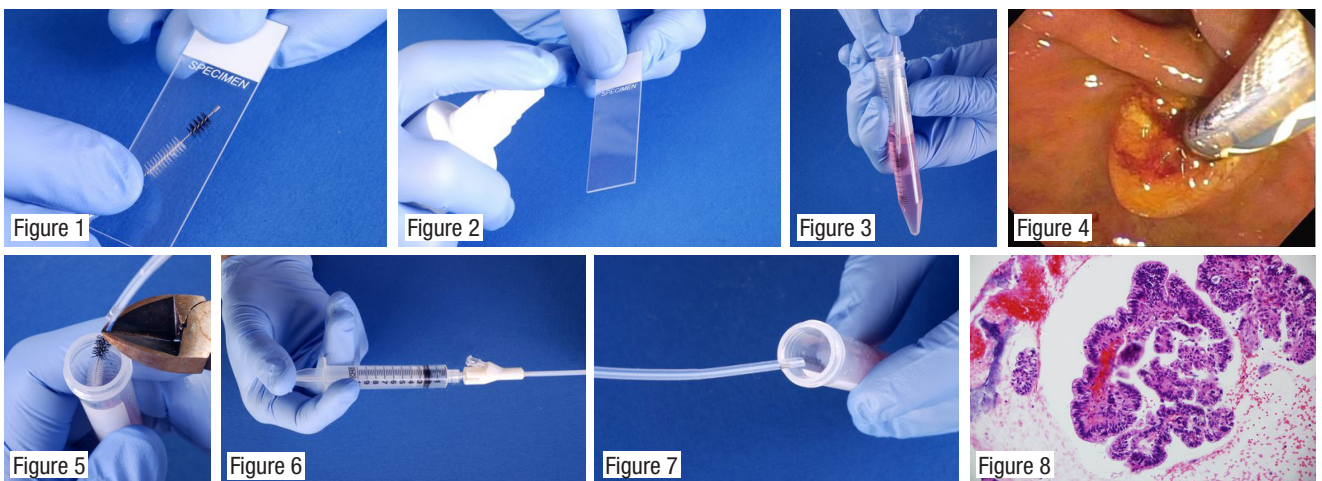
- » 26 suspected pancreatic adenocarcinoma
- » 8 suspected cholangiocarcinoma
- » 2 suspected gallbladder cancer

Most patients had confirmation of a malignant diagnosis by an alternative means of sampling (EUS-FNA, CT-FNA, bile duct biopsy, surgical histology).

Method

Two passes with the Infinity sampling device were performed to gather specimens from the targeted stricture. Two smears were prepared from the first pass, one of which was sprayed with fixative (Figures 1 & 2). The brush was then energetically agitated in the cytology fluid (RPMI) to dislodge material into the fluid (Figure 3). The brush was rinsed with water.

A second pass of brushing was performed (Figure 4). The brush was cut off and placed into the same tube of cytology fluid (Figure 5). Contents from the Infinity sampling device catheter were also placed into the cytology fluid via salvage cytology technique (Figures 6&7). The sample was processed as a cell block, and the cell block and smears were reviewed by the cytologist (Figure 8).



Results

The Infinity sampling device provided a positive diagnosis on 28/36 proven malignant strictures. This equates to a 78% Sensitivity.

Characteristic of Lesion	Number = 36	Infinity sampling device(pos or suspicious/neg)	Sensitivity
Pancreatic CA	26	20/6	77%
Gallbladder CA	2	1/1	50%
Cholangio CA	8	7/1	88%
Total	36	28/8	78%

Discussion

Though limited to 36 cases, a 78% positive diagnosis is excellent. In past experiences, using this same methodology, other brushes yield only 30-40%. The cell block frequently showed large samples of tissue. More cell block material was typically found using the Infinity device than FNA. The cytologist spontaneously said that the sample was "amazing" and that it resembles a biopsy more so than a cytology smear. There was plenty of material to do a full immunohistochemical workup of the specimen.

"The Infinity sampling device is clearly better than existing biliary brushes. The unique design of the brush was the reason I tried the device. The results are why my colleagues and I will continue to rely on it for our pancreatobiliary sampling needs."

ERCP Biliary Sampling

Gregory A. Cote, 2011⁶

Procedures

ERCP (endoscopic retrograde cholangiopancreatography) with indications for biliary sampling.

Indications

A total of 23 procedures were performed on bile duct strictures of suspected cancerous origin

- » 15 of these procedures were suspected to be cancerous (pancreatic tumor or cholangiocarcinoma)
- » 8 of the procedures were performed to monitor primary sclerosing cholangitis

Description

The Infinity sampling device was used to gather specimens from the targeted strictures. Using a therapeutic side-viewing scope, the device was passed over either an 0.025 or 0.035 guidewire. Positioning alongside of the targeted stricture was confirmed through fluoroscopy. Samples were gathered. The cellular matter was then prepared following the institutional guidelines. The device tip was cut and placed into a fixative material. In all of the cases, salvage cytology (flushing of the catheter) was utilized to collect additional specimens from the catheter.



1. Infinity sampling device design



2. Flushing capability for salvage cytology

Discussion

Functionally, the nurse was able to move the brush back and forth through the strictures with ease and the device displayed very well under fluoroscopy. In regard to design, there are a couple novel features that give it greater potential for a superior sample. The variable stiffness bristle design, to abrade the tissue and collect the sample, is a very nice concept. The gaps between the bristle segments offer the ability to capture more tissue in between those segments.

References:

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