BONAMEDA COOK Medical: Transluminal Biliary Biopsy

- During the past 2 decades, many studies have verified the safety, reliability, and cost effectiveness of percutaneous fine-needle aspiration biopsy (FNAB) in the nonsurgical tissue diagnosis of various abdominal diseases
- The advent of the automated biopsy device, or biopsy gun, has further improved the ability to obtain adequate specimens for histopathologic analysis
- In addition, advances in imaging techniques have enabled the use of biopsy in virtually all anatomic areas
- Nevertheless, this method of tissue diagnosis is also not fully justified for biliary tumors, because these tumors are often too
 small to allow an accurate percutaneous puncture to obtain appropriate material
- They are often desmoplastic, making it difficult to establish a histologic diagnosis
- For this reason, other biopsy methods have been proposed for improving the rate of diagnosis of malignant biliary tumors, such as:
 - Brushes
 - Forceps

Bile Duct: Analysis of Percutaneous Transluminal Forceps Biopsy in 130 Patients Suspected of Having Malignant Biliary Obstruction1

Gyoo-Sik Jung, MD, Jin-Do Huh, MD, Sang Uk Lee, MD, Byung Hoon Han, MD, Hee-Kyung Chang, MD, Young Duk Cho, MD

COOK Medical Transluminal Biliary Biopsy: PERCUTANEOUS BIOPSY IN BILIARY SYSTEM

- Bleeding complications
- Often difficult to target because lack of mass (very little amount of tumour tissue)
- Patients need to stop breathing
- 60% 80% accuracy
- High chance on false negatives
- Multiple procedures (first drainage, later biopsy)



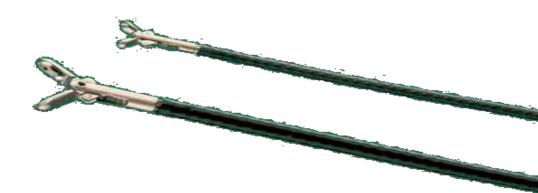
COOK Medical Transluminal Biliary Biopsy: TRANSLUMINAL BRUSHING

- Accuracy 30 50%
- Up to 70% false negatives



COOK Medical Transluminal Biliary Biopsy: OTHER OPTIONS?

- Biopsy forceps which are commonly used for e.g. for myocardial biopsy
- Results?
- First 14 patients: 50% sensitivity
- Why?

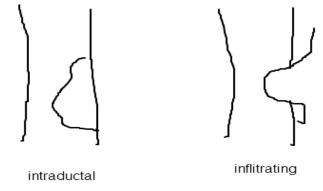


COOK Medical Transluminal Biliary Biopsy: PERCUTANEOUS BIOPSY BY FORCEPS

- Endocopic forceps are not wire guided, are not targeting, not steerable which results in 30 % sensitivity
- Brushing even worse with a sensitivity of 6 %
- Coaxial endoscoping (mother and baby- endoscope technique) allowing that mucosa can been seen but is very time consuming, very expensive and if tumor is far away, it's very difficult to target.
- Using endoscopic approach percutaneously seems inappropriate as it will need a channel of 16 French while
 PTCD needs only 8,5 French
- Patient selection is very important:
 - No visible mass= probability of malignancy is very high
 - Patients with unclear jaundice
 - B II patients
 - Patients with gastric cancer
 - Whipple patients

COOK Medical Transluminal Biliary Biopsy: KEY POINTS TO SUCCESS

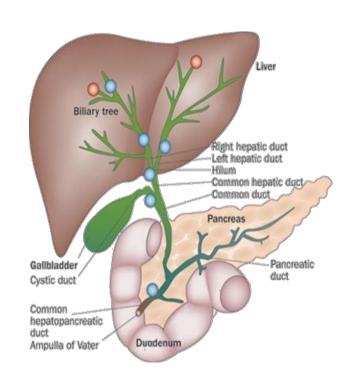
 Method is "easy" to learn but still has a learning curve! To cross the lesion is the most difficult part but mandatory for success





- So Improvements achieved by both are better but still not satisfying!
- Furthermore, those patients suffer on jaundice of (so far) unknown origin which needs to be treated
- PTBD is a well-established interventional radiologic procedure to treat patients with obstructive jaundice
- It can also be used to provide access to the intrahepatic and extrahepatic bile
- Duct for various biopsy instruments

- Cross lesion with wire guide to establish pathway control
- Work with long sheath = precise and stable position in target area
- Use the sheath as a pusher = directional control
- Biopsy of the obstruction, even in very small amount of tissue



COOK Medical Transluminal Biliary Biopsy: RESULTS IMPROVED SIGNIFICANTLY

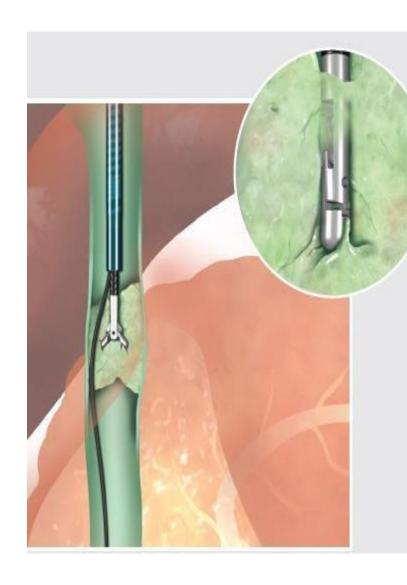
- Out of next 48 patients, 44 patients were diagnosed correctly!
- Calculated accuracy for biopsies performed with pushing technique:

48 correctly diagnosed out of 52

Accuracy 92,3%!!! (compared with percutanous biopsy of ~60 %)

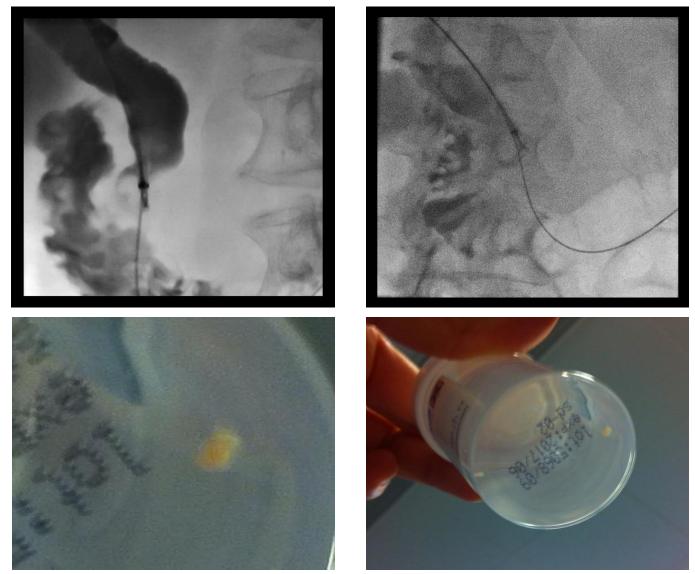
COOK Medical Transluminal Biliary Biopsy: KEY TO SUCCESS

- Pass the obstruction with guide wire and manipulation catheter to <u>CROSS THE LESION!</u>
- Put tip of Flexor sheath in front of obstruction while leaving the wire accross the obstruction
- Advance forceps through Flexor <u>alongside</u> the guide wire, open forceps
- PUSH!!! the HOLT opened forceps by tip of sheath into obstruction and take sample (3 times)
- CROSS and PUSH technique is the key to success!
- Place drainage catheter or stent over the wire



TRANSLUMINAL BILIARY ACCESS AND BIOPSY FORCEPS SET

- Biopsy forceps allow single-handed torque control to achieve ideal cutting position without tip deflection.
- All components necessary to access the biliary tree for both percutaneous transhepatic cholangiography and transluminal biopsy are included.
- Cook's separate, complementary line of biliary drains and stents allows physicians to complete the procedure according to their preference.

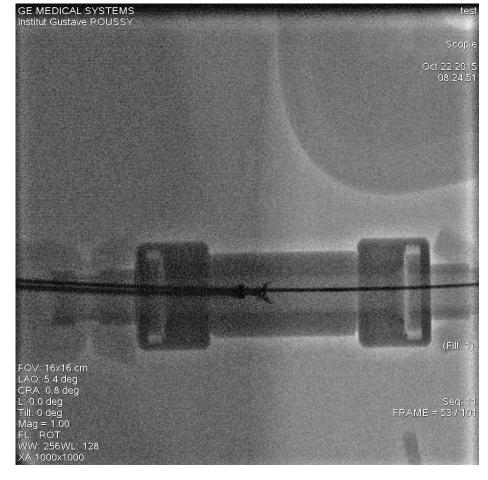


INNOVATIVE MEDICAL SOLUTIONS

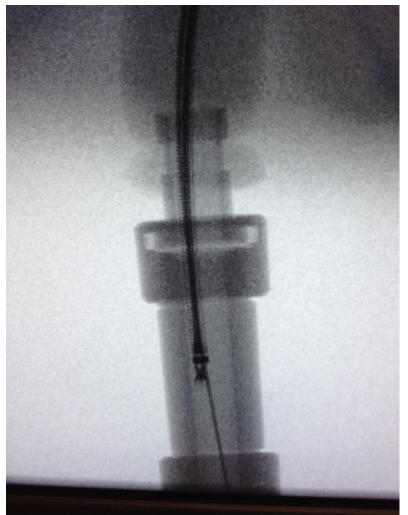


















Biopsy forceps 7French "Safety" wire

Usefulness and safety of biliary percutaneous transluminal forceps biopsy (PTFB): our experience

40 biopsies

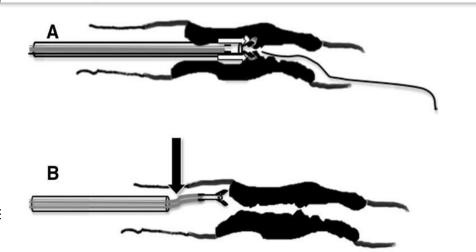
21 diagnosed malignancy, 13 diagnosed proven true-negative

6 false-negative (15%)

0 false-positive

(Ierardi AM, Minimally Invasive Therapy. 2013)

Improved Accuracy of Percutaneous Biopsy Using "Cross and Push" Technique for Patients Suspected with Malignant Biliary Strictures



Sensitivuty: 93.3% Accuracy: 94.2%,

<u>Cardiovasc Intervent Radiol</u>. 2015 Aug;38(4):1005-10. doi: 10.1007/s00270-014-0976-0. Epub 2014 Sep 6.

Improved Accuracy of Percutaneous Biopsy Using "Cross and Push" Technique for Patients Suspected with Malignant Biliary Strictures.

Patel P₁, Rangarajan B, Mangat K.

INNOVATIVE MEDICAL S

CONTACTS FOR MORE QUESTIONS

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