DDW 2022: Interventional Endoscopy : ERCP

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June 4, 2022
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Disclosures

- Boston Scientific, Consultant
- Olympus America, Consultant

Objectives

- Impact of disposable elevator caps on the rate of duodenoscope contamination
- Hemostasis with a novel gel after endoscopic sphincterotomy and papillectomy
- Intraductal hydrodynamic gene delivery to the pancreas
- The role of a convolutional neural network in classification of biliary strictures
- Expert endoscopists vs. artificial intelligence in the evaluation of indeterminate biliary strictures

Sterile Disposable Elevator Cap (DEC) Significantly Reduces Rate of Persistent Duodenoscope Contamination After Reprocessing: Outcomes From a Prospective Surveillance Trial

Bhakta D, Joseph-Talreja M, DaVee T, Wadhwa V, Ramireddy S, Rashtak S, Guha S, Patil P, Ostrosky L, and Thosani N.

The University of Texas Health Science Center at Houston John P and Katherine G McGovern Medical School, Houston, Texas

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Sterile Disposable Elevator Cap (DEC) Significantly Reduces Rate of Persistent Duodenoscope Contamination After Reprocessing: Outcomes From a Prospective Surveillance Trial

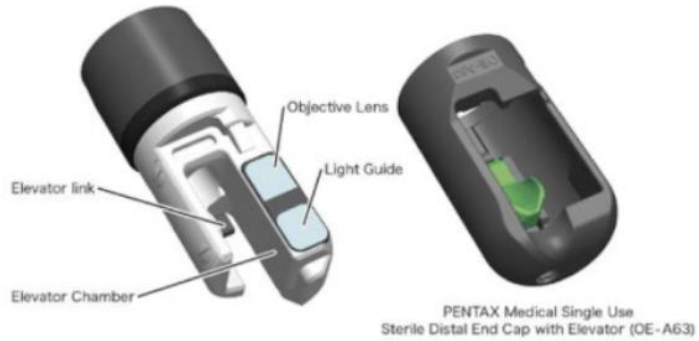
- Ongoing concerns regarding healthcare associated infections related to ERCP
- Semi disposable and disposable duodenoscopes
- Limited data regarding rate of post reprocessing persistent contamination with use of DEC
- Ongoing prospective surveillance trial comparing DEC with conventional duodenoscopes without DEC

Bhakta D, Joseph-Talreja M, DaVee T, et. al. The University of Texas Health Science Center at Houston John P and Katherine G McGovern Medical School

Sterile Disposable Elevator Cap (DEC) Significantly Reduces Rate of Persistent Duodenoscope Contamination After Reprocessing: Outcomes From a Prospective Surveillance Trial

- Sampling of the reprocessed duodenoscope was performed using standardized FDA recommended protocol
  - **Prior to 3/2021:** culture data obtained from standard duodenoscope without a DEC (Pentax ED-3490TK)
  - **After 3/2021:** culture data obtained from duodenoscopes with a DEC (Pentax ED34-i0T2)
  - Four separate culture specimens were obtained from four locations on each scope using a sterile brush
    - Surface of duodenoscope
    - Elevator in open position
    - Elevator in closed position
    - Fluid obtained after sterile water flushing at the scope channel
  - Culture data divided into 3 categories further subdivided
    - Low to moderate concern organisms with < 100 CFU
    - Low to moderate concern organisms with >100 CFU
    - High concern organisms

Image 1: Duodenoscope Disposable Elevator Cap (Pentax ED34-i10T2)



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Sterile Disposable Elevator Cap (DEC) Significantly Reduces Rate of Persistent Duodenoscope Contamination After Reprocessing: Outcomes From a Prospective Surveillance Trial

- 108 duodenoscopes
  - 16 samples collected from duodenoscopes without a DEC
  - 92 samples from duodenoscope with a DEC
- Conventional duodenoscope
  - 13/16 (81.3%) returned positive for growth
    - 12/13 (75%) category 1
    - 0 (0%) category 2
    - 1 (6.3%) category 3
- DEC duodenoscope
  - 22/92 (23.9%) returned positive for growth
    - 22/22 (100%) category 1
- DEC duodenoscopes
  - Significantly lower rate of contamination overall (23.9% vs. 81.3%, p value < 0.01)
  - Significantly lower for high concern organisms (0% vs. 6.3%, p value 0.015)

Table 1: Duodenoscope with and without Disposable Elevator Cap: Culture Data

	Conventional Duodenoscope	DEC Duodenoscope	z-score	p-value
Samples (n)	16	92	-	-
Positive Culture (n) (%)	13 (81.30%)	22 (23.90%)	4.523	<0.01*
Culture with low to moderate concern organism < 100 CFU (n) (%)	12 (75%)	22 (100%)	4.061	<0.01*
Culture with low to moderate concern organism > 100 CFU (n) (%)	0 (0%)	0 (0%)	-	-
Culture with any high concern organism (n) (%)	1 (6.30%)	0 (0%)	2.409	0.015*

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Sterile Disposable Elevator Cap (DEC) Significantly Reduces Rate of Persistent Duodenoscope Contamination After Reprocessing: Outcomes From a Prospective Surveillance Trial

- DEC duodenoscopes significantly reduces rate of persistent contamination for any growth as well as high concern organisms after reprocessing
- Novel design is cost effective
- Can likely prevent further outbreaks related to ERCP procedures

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Efficacy and Safety of Novel Hemostatic Gel in Endoscopic Sphincterotomy or Endoscopic Papillectomy: A Multicenter, Single-Blinded Prospective, Randomized Controlled Clinical Trial

Choi J, Cho I, Lee S, Kim J, Park N, Lee M, Jang D, Paik W, Ahn DW, Ryu J, Kim YT, Kim E, and Lee J.

Dongguk University Ilsan Hospital, Goyang, Korea

Seoul National University Seoul Metropolitan Government Boramae Medical Center, Seoul, Korea

CG Bio Co., Ltd, Seoul, Korea

Seoul National University Hospital, Seoul, Korea

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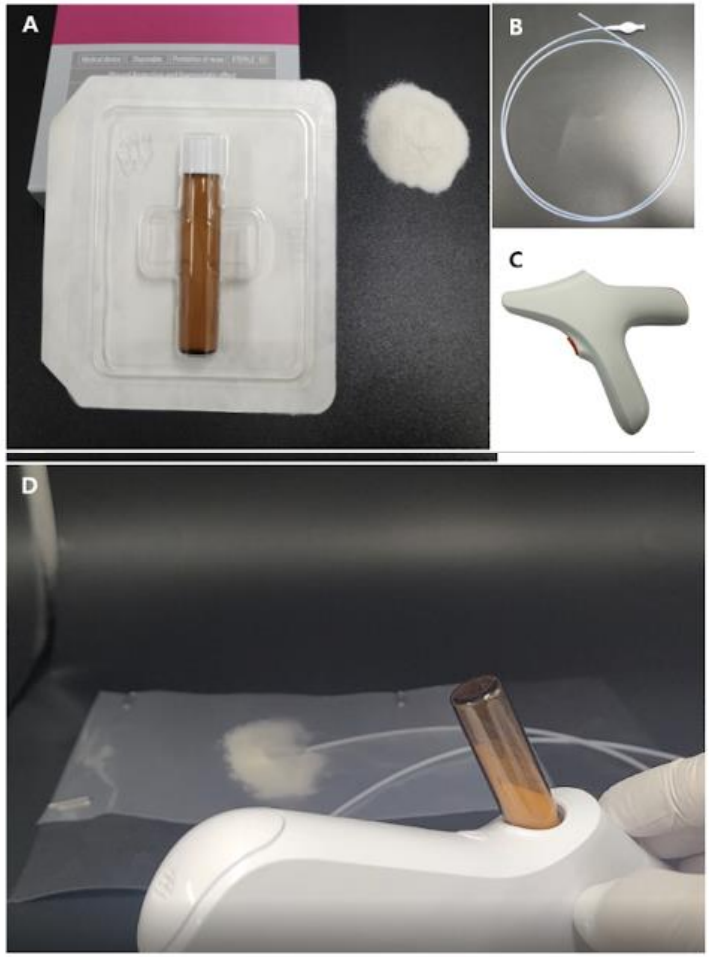
Efficacy and Safety of Novel Hemostatic Gel in Endoscopic Sphincterotomy or Endoscopic Papillectomy: A Multicenter, Single-Blinded Prospective, Randomized Controlled Clinical Trial

- Post-procedural bleeding is one of the most common adverse events after endoscopic sphincterotomy (EST) or papillectomy (EP)
- Traditional hemostatic methods with side viewing duodenoscopes can be challenging for endoscopists
- Randomized control trial evaluating the efficacy and safety of novel hemostatic gel for patients who experience post EST or EP bleeding in comparison to epinephrine spray



Choi J, Cho I, Lee S, et al. Dongguk University Ilsan Hospital, Goyang, Korea

Efficacy and Safety of Novel Hemostatic Gel in Endoscopic Sphincterotomy or Endoscopic Papillectomy: A Multicenter, Single-Blinded Prospective, Randomized Controlled Clinical Trial

- Multicenter, subject-blind, randomized trial 11/2020-12/21 at two tertiary care centers in South Korea
- Pts with immediate bleeding after EST or EP were enrolled
  - Allocated to either primary hemostasis with novel hemostatic gel or epinephrine spray
- Study outcomes
  - Success rate of primary hemostasis for immediate post-procedural bleeding
  - Rate of delayed bleeding

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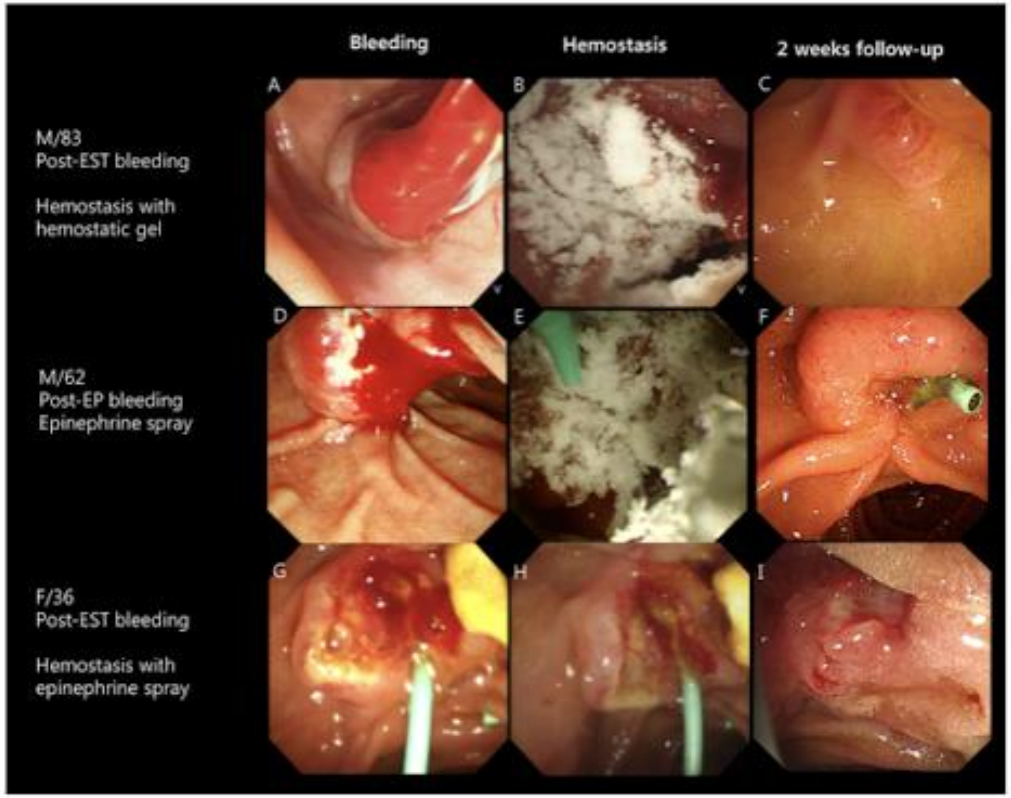
Efficacy and Safety of Novel Hemostatic Gel in Endoscopic Sphincterotomy or Endoscopic Papillectomy: A Multicenter, Single-Blinded Prospective, Randomized Controlled Clinical Trial

- 84 patients enrolled
  - Two excluded due to drop out
  - 41 patients in each group were analyzed
- Hemostatic gel showed significant superior successful primary hemostasis than epinephrine spray ($p = 0.026$)
  - Hemostatic gel 100%
  - Epinephrine spray 85.4%
- No significant statistical differences between two agents in delayed bleeding ($p = 0.329$)
  - Hemostatic gel 2.4%
  - Epinephrine spray 7.3%
- Mean hemostatic procedural time was significantly longer in the hemostatic gel ($p < 0.001$)
  - Hemostatic gel (3.23 ± 1.94 min)
  - Epinephrine spray (1.76 ± 0.99)
- There were no differences in adverse events related to each hemostatic agent

Choi J, Cho I, Lee S, et al. Dongguk University Ilsan Hospital, Goyang, Korea

Efficacy and Safety of Novel Hemostatic Gel in Endoscopic Sphincterotomy or Endoscopic Papillectomy: A Multicenter, Single-Blinded Prospective, Randomized Controlled Clinical Trial

- The novel hemostatic gel is expected to ensure satisfactory hemostatic results while making hemostasis for immediate post-EST or post-EP bleeding easier



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Gene Delivery into the Pancreas of Pig by Non-viral, Ductal Hydrodynamic Injection

Huang Y, Kruse R, and Kumbhari V.

The Johns Hopkins Hospital, Baltimore Maryland

Mayo Clinic, Jacksonville FL

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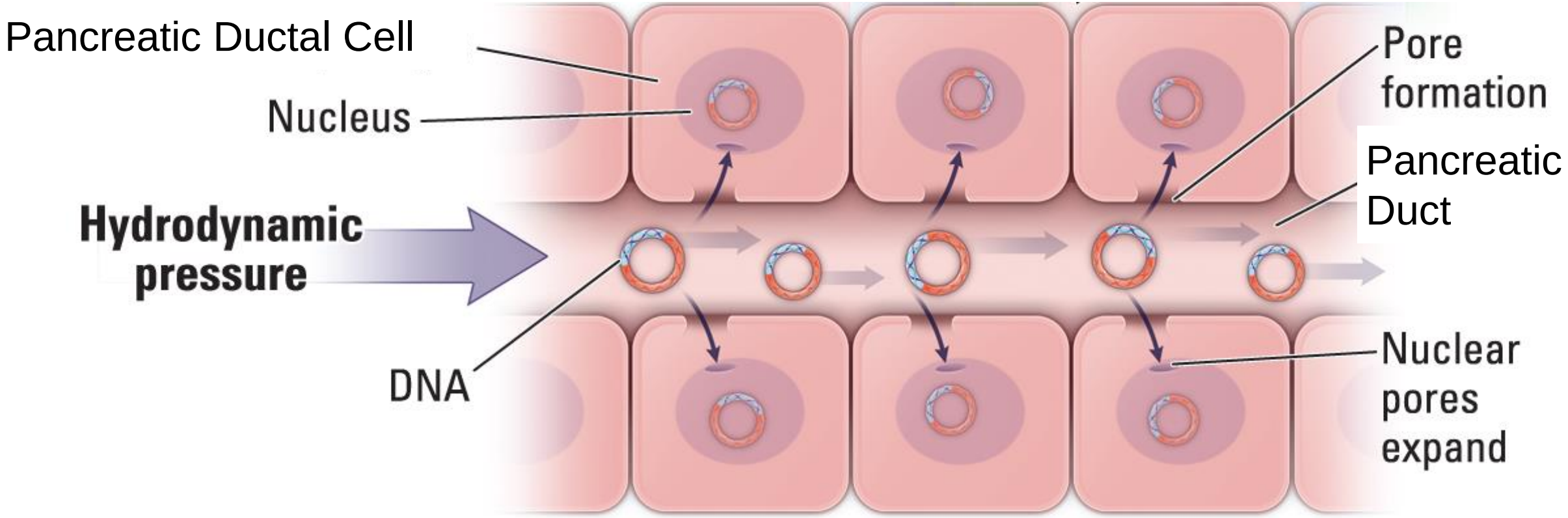
Gene Delivery into the Pancreas of Pig by Non-viral, Ductal Hydrodynamic Injection

- Gene therapy of the pancreas is a potential modality for a variety of diseases (AI DM, genetic chronic pancreatitis, PDAC)
- Proof of concept studies employing viral vectors have achieved modest delivery efficiency into the pancreas of rodents through a variety of different routes
- Gene delivery into the pancreas of a human-sized, large animal model has not been achieved

Huang Y, Kruse R, Kumbhari V. The Johns Hopkins Hospital, Baltimore Maryland, Mayo Clinic, Jacksonville FL

Gene Delivery into the Pancreas of Pig by Non-viral, Ductal Hydrodynamic Injection

Hydrodynamic gene delivery as an alternative to viral vectors



Adapted from Kruse, Huang, et al. GIE 2021

Huang Y, Kruse R, Kumbhari V. The Johns Hopkins Hospital, Baltimore Maryland, Mayo Clinic, Jacksonville FL

Gene Delivery into the Pancreas of Pig by Non-viral, Ductal Hydrodynamic Injection

Pancreatic Ductal Hydrodynamic Injection

- Ductal system contacts all aspects of the pancreatic tissue through a single access point.
- Uni-directional and closed, easier to create pressure to delivery DNA.
- 5 pigs with similar weight to human for clinical feasibility
- For proof of concept, employed a plasmid DNA encoding firefly luciferase (Fluc) and green fluorescent protein (GFP) under ubiquitous CMV and SV4-promoters, respectively.

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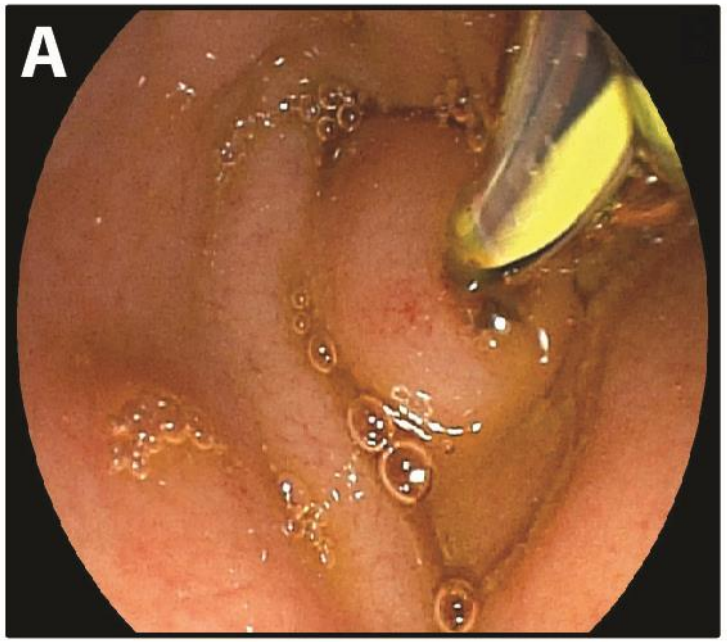
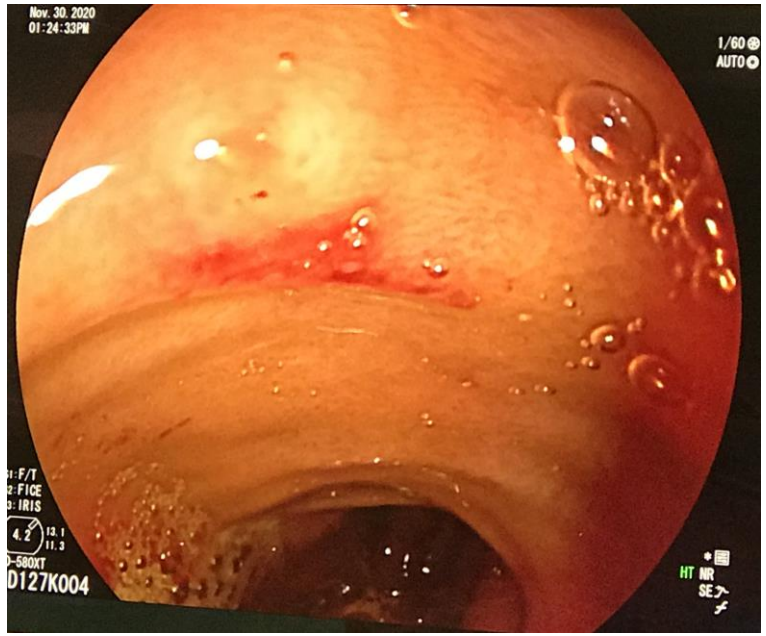
Gene Delivery into the Pancreas of Pig by Non-viral, Ductal Hydrodynamic Injection

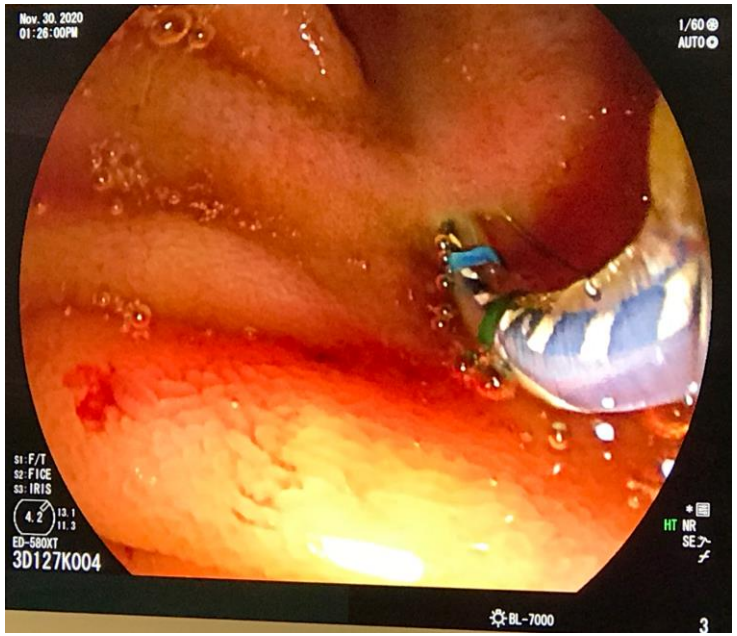
Endoscopic localization of pig pancreatic duct



Canulation of Ampulla of Vater in pigs (biliary system)



Separate pancreatic duct orifice in pigs



Cannulation of pancreatic duct orifice in pigs

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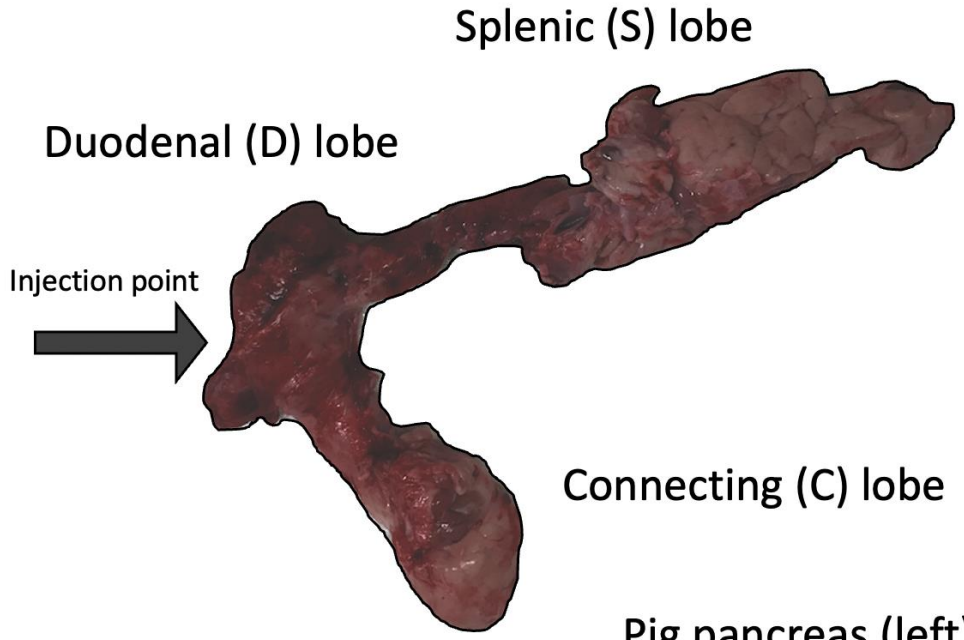
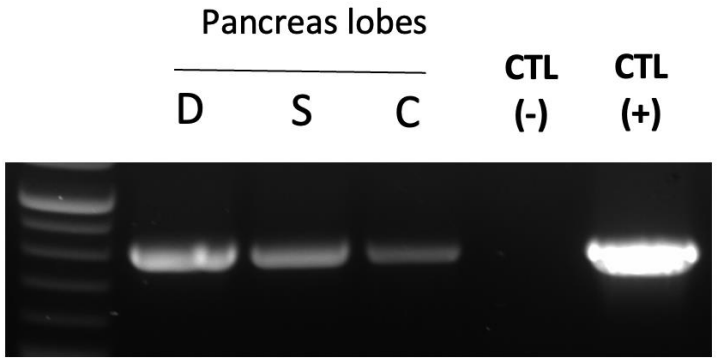
Gene Delivery into the Pancreas of Pig by Non-viral, Ductal Hydrodynamic Injection

DNA can be detected in all pancreatic lobes





Pig pancreas (left) harvested 1 day post-injection. PCR (right) shown from one representative pig.

Huang Y, Kruse R, Kumbhari V. The Johns Hopkins Hospital, Baltimore Maryland, Mayo Clinic, Jacksonville FL

Gene Delivery into the Pancreas of Pig by Non-viral, Ductal Hydrodynamic Injection

- All pigs tolerated ERCP mediated injection well
  - VS stable
  - No anemia or leukocytosis
  - Transient elevation of amylase on day 1 post-injection that normalized on day 3

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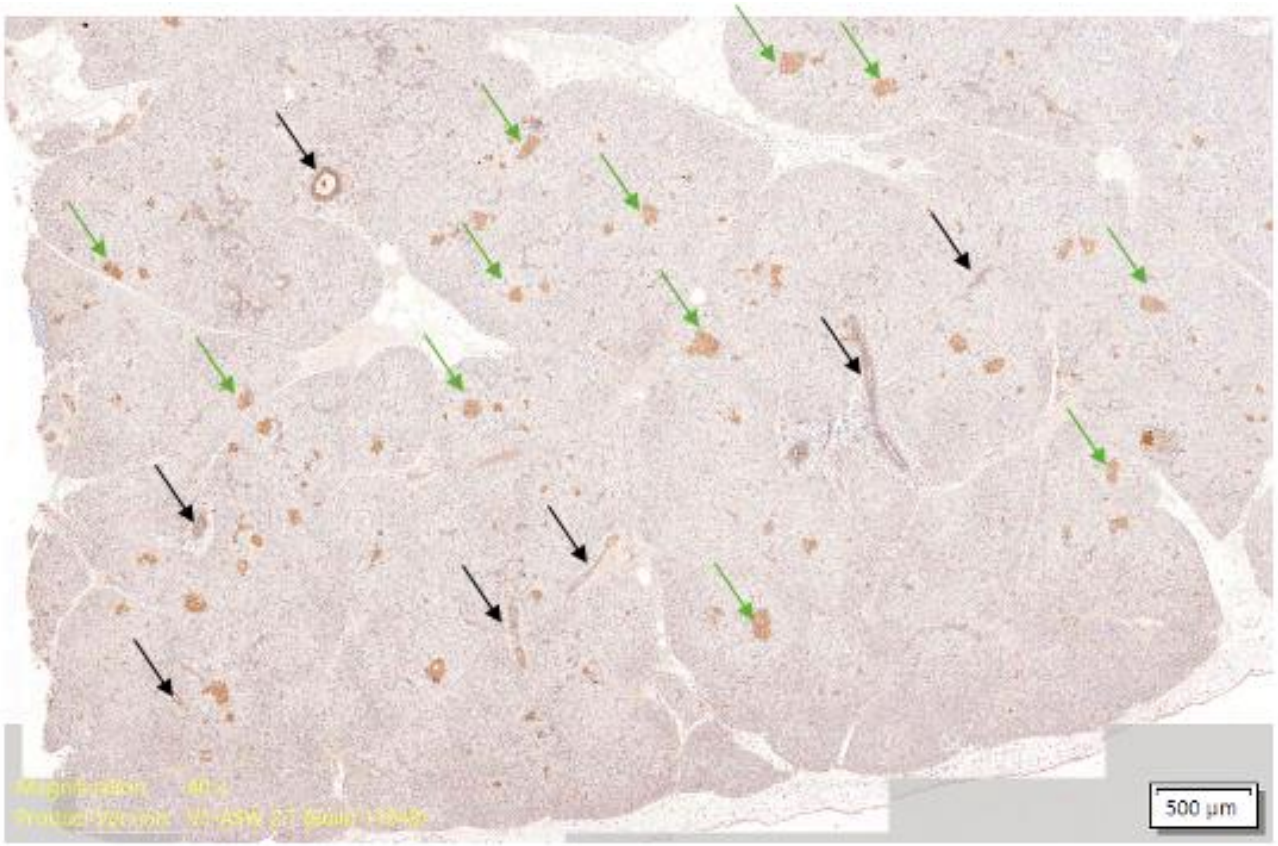
Gene Delivery into the Pancreas of Pig by Non-viral, Ductal Hydrodynamic Injection

Virtually all islets and ductal cells express the delivered luciferase gene



↘ = Ductal cell

↘ = Islet cell

Same pattern observed in all pancreas lobes, across all pigs

Acinar cells do not express gene here, possibly due to lack of promoter activity in that cell type.

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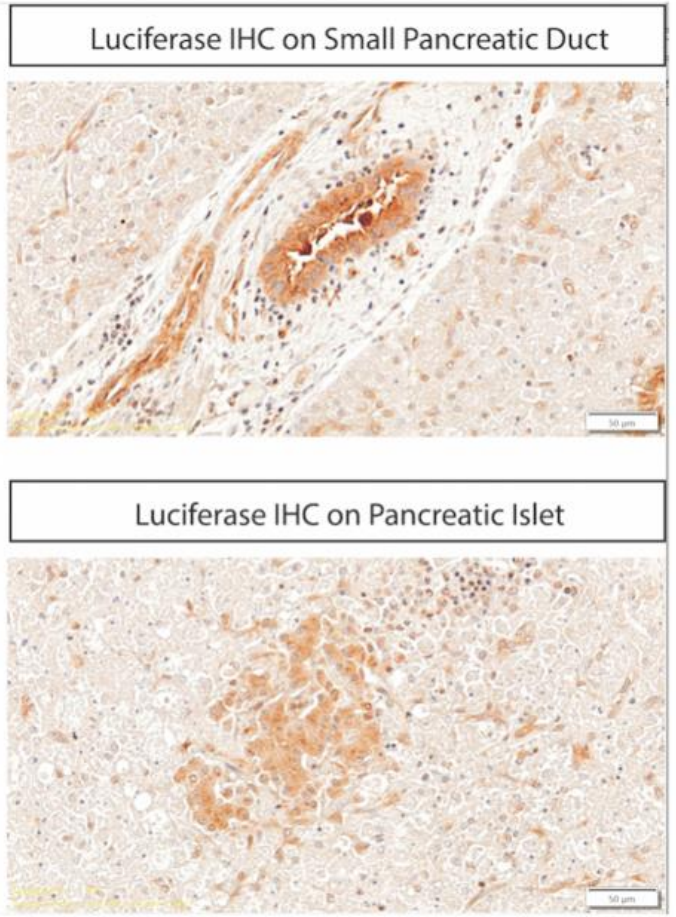
Gene Delivery into the Pancreas of Pig by Non-viral, Ductal Hydrodynamic Injection

- Different pancreatic cell types were transfected at high efficiencies with expression observed in islet cells and ductal cells, as well as acinar cells, endothelial cells, and neurons



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Gene Delivery into the Pancreas of Pig by Non-viral, Ductal Hydrodynamic Injection

- Reports the first gene delivery into the pancreas of a human-sized, large animal model
- ERCP can access the pancreatic duct, whereafter hydrodynamic delivery can directly deliver DNA into multiple cell types
- While there were no episodes of pancreatitis, additional work is needed to verify the potential risk of pancreatitis, which is a major consideration for human translation
- Future studies will investigate the ability of ductal hydrodynamic gene delivery to treat pancreatic diseases in animal models

Huang Y, Kruse R, Kumbhari V. The Johns Hopkins Hospital, Baltimore Maryland, Mayo Clinic, Jacksonville FL

Development and Validation of a Cholangioscopy Convolutional Neural Network Capable of Video Analysis and Accurate Classification of Biliary Strictures

Marya N, Powers P, Peterson B, Law R, Storm A, Abusaleh R, Rau P, Stead C, Levy M, Martin J, Vargas E, Abu Dayyeh B, and Chandrasekhara V.

University of Massachusetts Medical School, Worcester, MA

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Development and Validation of a Cholangioscopy Convolutional Neural Network Capable of Video Analysis and Accurate Classification of Biliary Strictures

- Current ERCP-based modalities have low diagnostic accuracy for the classification of biliary pathology
- Expert visual interpretation of biliary strictures via POC has been demonstrated to be more accurate than brush cytology (BC) or forceps biopsies (FB), but is subject to high interobserver variability and low rates of agreement
- Aim: develop and validate a POC-convolutional neural network (CNN) capable of accurate diagnosis of biliary strictures and compare it to current ERCP based modalities

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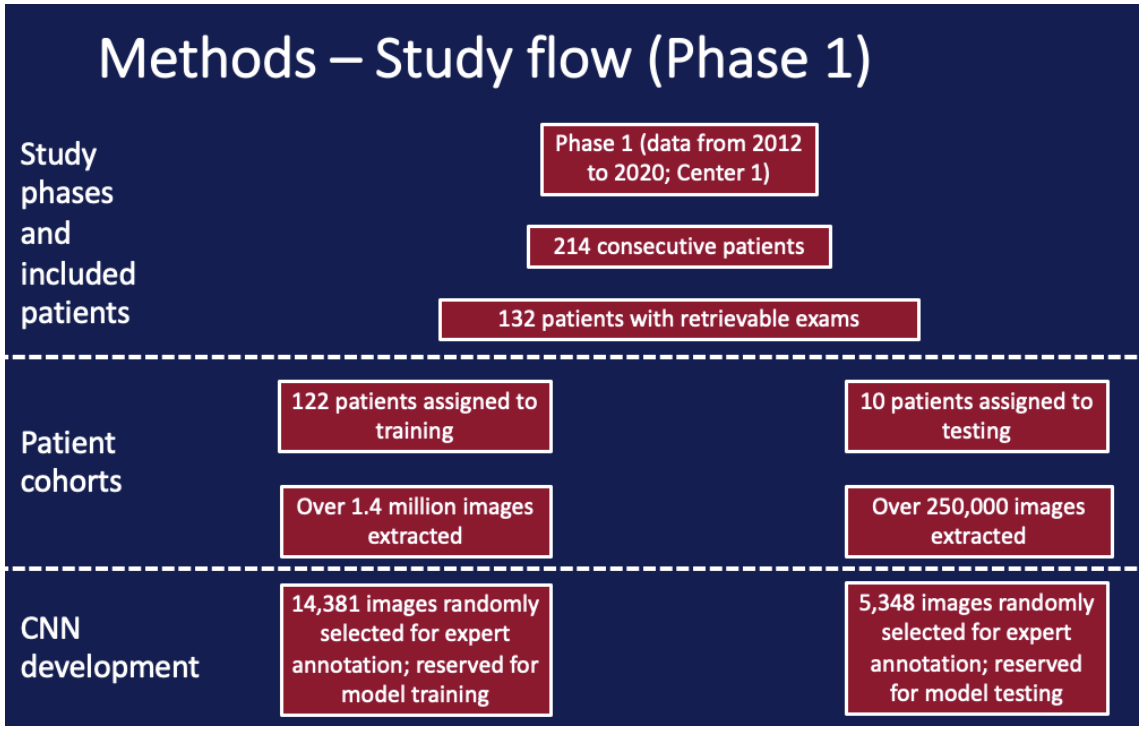
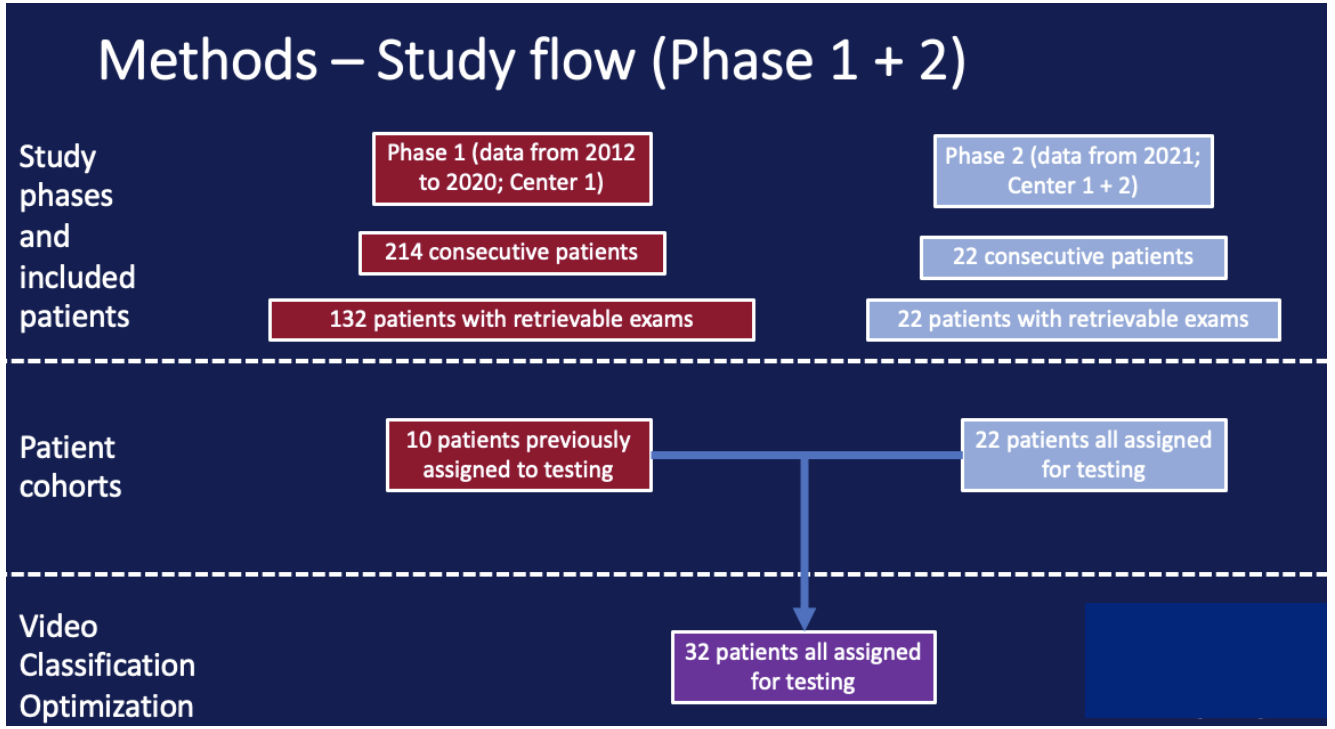
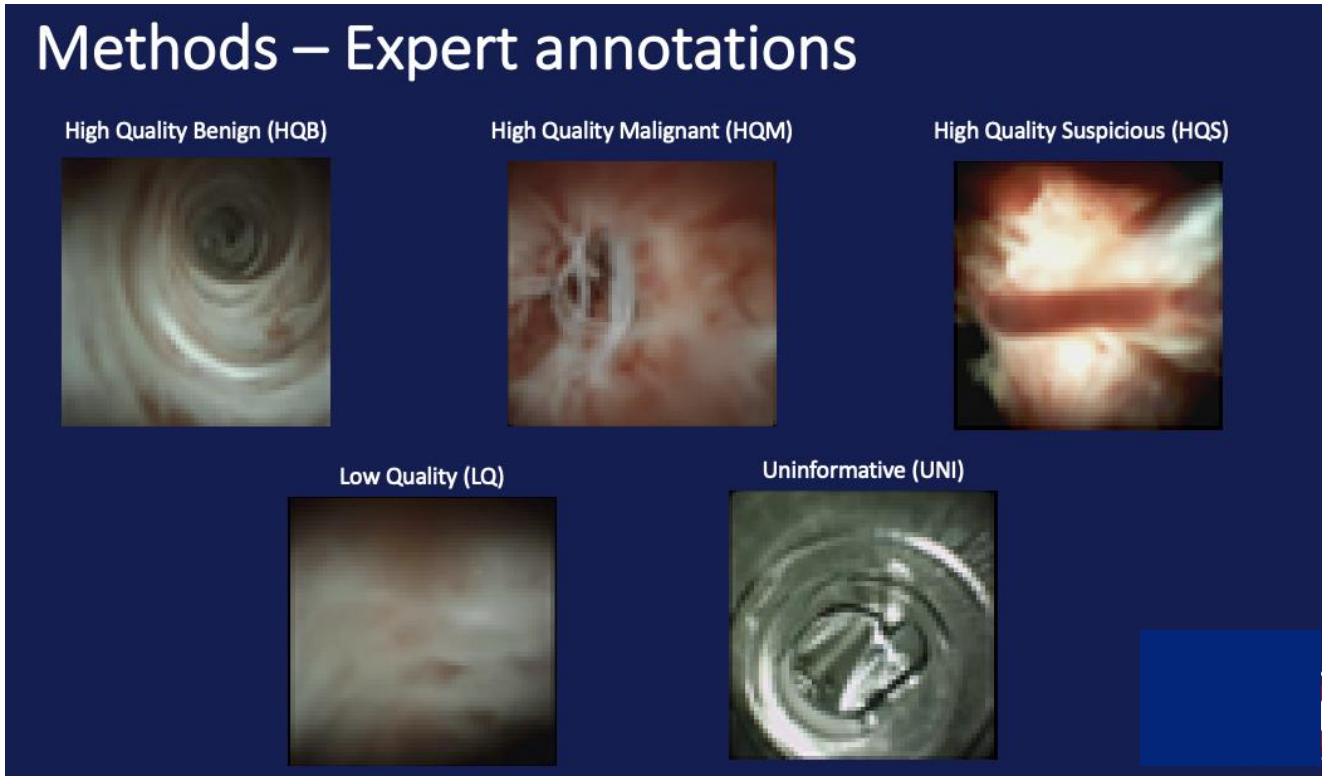
Development and Validation of a Cholangioscopy Convolutional Neural Network Capable of Video Analysis and Accurate Classification of Biliary Strictures





Development and Validation of a Cholangioscopy Convolutional Neural Network Capable of Video Analysis and Accurate Classification of Biliary Strictures

From the training cohort, 20.000 stills were randomly extracted and annotated by a blinded experts



Marya N, Powers P, Peterson B, et. al. University of Massachusetts Medical School, Mayo Clinic Minnesota

Development and Validation of a Cholangioscopy Convolutional Neural Network Capable of Video Analysis and Accurate Classification of Biliary Strictures

- A ResNet 50 CNN generated a model designed to mimic expert annotation.
- A regression model determined POC-CNN classification scores across whole videos associated with greatest classification accuracy
- The POC-CNN video analysis threshold was applied to the reserved test set.
- POC-CNN performance on the total reserved test set was compared to the performance of BC and FB (combined transpapillary and cholangioscopy-directed forceps).

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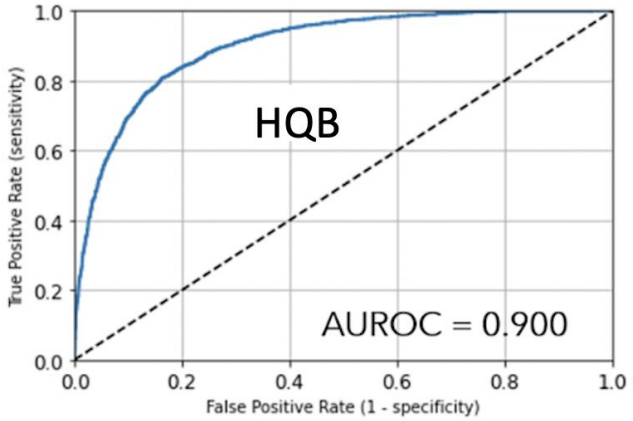
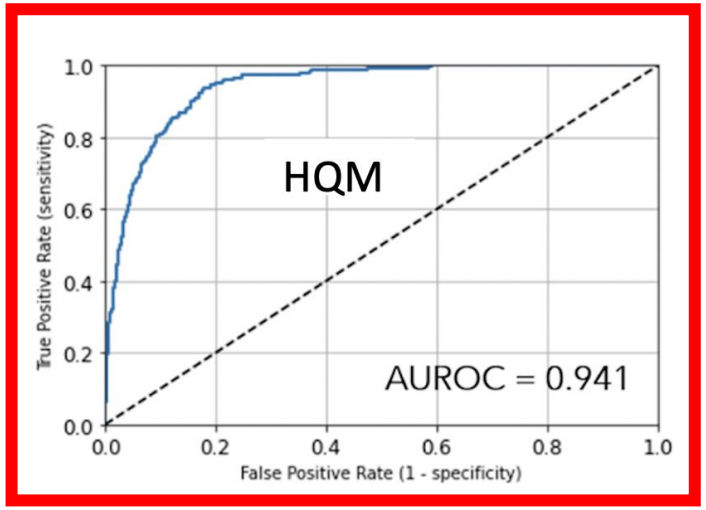
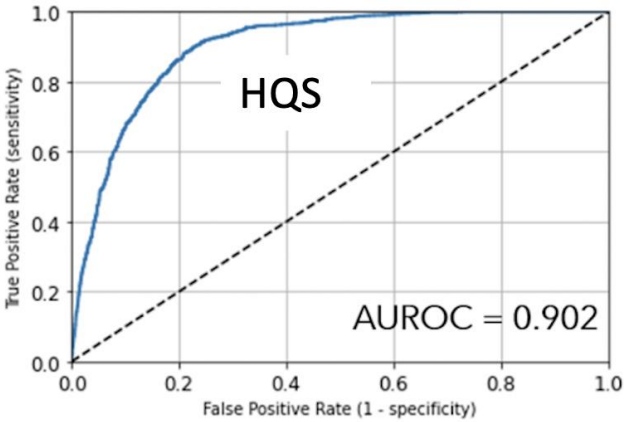
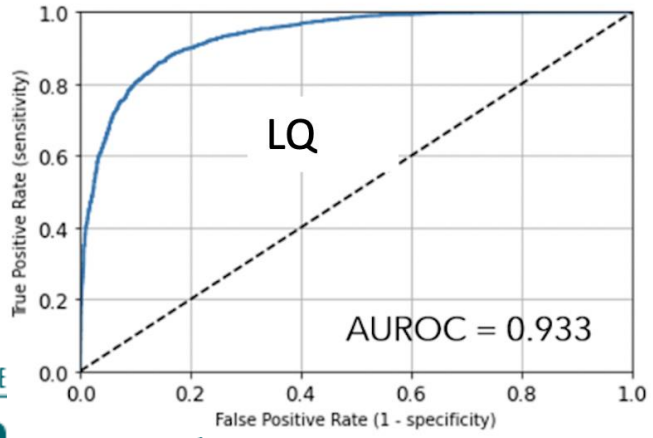
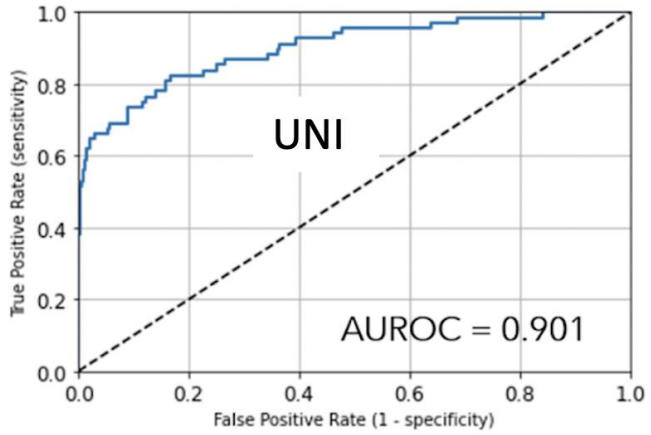
Results – CNN performance based on expert annotations







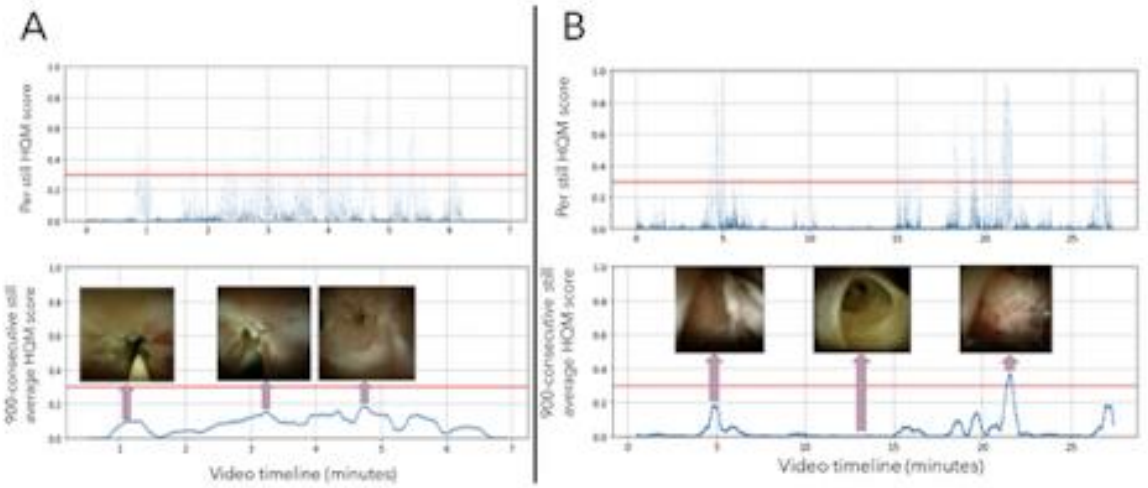




Development and Validation of a Cholangioscopy Convolutional Neural Network Capable of Video Analysis and Accurate Classification of Biliary Strictures

A POC-CNN HQM average score across 900 consecutive still images demonstrated greatest video biliary classification accuracy

Number of consecutive stills	AUROC	Sensitivity	Specificity	Accuracy
1800-max (HQM)	0.929	0.933	0.824	0.875
900-max (HQM)	0.942	0.933	0.882	0.906
300-max (HQM)	0.900	0.933	0.824	0.875
30-max (HQM)	0.912	0.933	0.765	0.844
1-max (HQM)	0.883	0.867	0.823	0.844



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Development and Validation of a Cholangioscopy Convolutional Neural Network Capable of Video Analysis and Accurate Classification of Biliary Strictures

Results – AI video analysis versus FB or BC

- For per-patient video analysis, the POC-CNN biliary classification was **100% sensitive and 100% specific** when applied to 7 videos from the external center.
- In total, when applied to the entire test set, the specificity of POC-CNN (87%) was similar to that of brush cytology (100%; p = 0.53) and forceps biopsy (100%); p = 0.51).
- However the **sensitivity of the POC-CNN (91%)** was significantly greater than that of BC (36%; p = 0.02) and FB (36%; p = 0.02)

Development and Validation of a Cholangioscopy Convolutional Neural Network Capable of Video Analysis and Accurate Classification of Biliary Strictures

- Study demonstrates that a POC-CNN run on cholangioscopy videos is capable of accurately diagnosing biliary strictures, with similar specificity, but greater sensitivity than existing ERCP based sampling modalities.

Expert Endoscopists vs. Artificial Intelligence in the Evaluation of Undetermined Biliary Strictures in Cholangioscopy: A Multi-Center Blinded Nested Control Trial

Robles-Medranda C, Alcivar-Vasquez J, Kahaleh M, Raijman I, Kunda R, Tyberg A, Sarkar A, Shahid H, Mendez J, Rodriguez J, Puga-Tejada M, Arevalo-Mora M, Calle-Loffredo D, Alvarado J, and Pitanga Lukashok H

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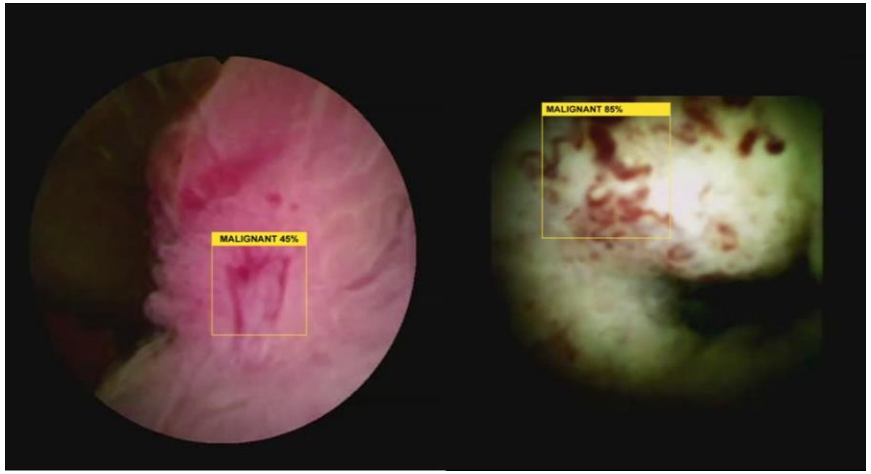
Expert Endoscopists vs. Artificial Intelligence in the Evaluation of Undetermined Biliary Strictures in Cholangioscopy: A Multi-Center Blinded Nested Control Trial

- Digital single-operator cholangioscopy (DSOC) findings achieve high diagnostic accuracy for neoplastic bile duct lesions
- Endoscopists' intra- and inter-observer agreements vary widely, and no universally accepted DSOC classification is available.
- Recently proposed an AI model to classify bile duct lesions during real-time DSOC, which accurately detected malignancy patterns.
- Aim: Clinical validation of AI model for distinguishing between neoplastic and non-neoplastic bile duct lesions compared with high DSOC experienced endoscopists.

Robles-Medranda C, Alcivar-Vasquez J, Kahaleh M. et al. Instituto Ecuatoriano de Enfermedades Digestivas

Expert Endoscopists vs. Artificial Intelligence in the Evaluation of Undetermined Biliary Strictures in Cholangioscopy: A Multi-Center Blinded Nested Control Trial

- Four DSOC expert endoscopists (blinded to clinical records), observed and classified a set of videos among neoplastic or non-neoplastic bile duct lesions
- All videos were unknown for DSOC experts and for the AI software (mdconsgroup, Guayaquil, Ecuador).
- The neoplastic bile duct criteria were in accordance with Robles-Medranda et al. and Mendoza classifications.
- The experts assessed neoplastic bile duct by presence or absence of disaggregated criteria.
- The statistical software computed disaggregated answers.
- The final diagnosis of malignancy was based on histological results, and 1-year clinical follow-up outcomes (blinded for AI and DSOC experts).



Real-time characterization of a biliary stricture during a DSOC evaluation using the developed artificial intelligence model. The bounding box represents the area suggestive of malignancy within the biliary lesion.

Robles-Medranda C, Alcivar-Vasquez J, Kahaleh M. et al. Instituto Ecuatoriano de Enfermedades Digestivas, Ecuador

Expert Endoscopists vs. Artificial Intelligence in the Evaluation of Undetermined Biliary Strictures in Cholangioscopy: A Multi-Center Blinded Nested Control Trial

- 170 videos from 170 patients from 4 different centers were analyzed with the AI model
- DSOC indication
  - 58/170 (34.1%) with suspicion of tumor
  - 46/170 (27.1%) with indeterminate stenosis
  - 31/170 (18.2%) with indeterminate dilation
  - 35/170 (20.6%) with a filling defect
- Stricture locations
  - Common bile duct (48)
  - Hilum (48)
  - Common hepatic duct (70)
  - Intrahepatic duct (4)
- There was an equal distribution among neoplastic and non-neoplastic DSOC diagnosis.

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Expert Endoscopists vs. Artificial Intelligence in the Evaluation of Undetermined Biliary Strictures in Cholangioscopy: A Multi-Center Blinded Nested Control Trial

- The most prevalent biopsy diagnosis:
  - Inflammatory 69/170 (40.6%)
  - Cholangiocarcinoma 67/170 (39.4%)
- DSOC AI software achieved significant accuracy values for neoplastic diagnosis:
  - ≥ 90% sensitivity
  - ≥ 60% specificity
  - ≥ 70% positive
  - ≥ 85% negative predictive values
- DSOC AI software accuracy is comparable and even statistically higher than endoscopist expert.

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	Sensitivity	Specificity	PPV	NPV	Agreement	ROC curves
Expert 1 (n=94)						
CRM criteria	27/48; 56.25 (41.18 - 70.52)	19/46; 41.3 (27 - 56.77)	27/54; 50 (36.08 - 63.92)	19/40; 47.5 (31.51 - 63.87)	46/94; 48.94 (38.48 - 59.46)	0.51
Mendoza criteria	46/48; 95.83 (85.75 - 99.49)	2/46; 4.35 (0.53 - 14.84)	46/90; 51.11 (40.35 - 61.8)	2/4; 50 (6.76 - 93.24)	48/94; 51.06 (40.54 - 61.52)	0.51
AI	47/48; 97.92 (88.93 - 99.95)	32/46; 69.57 (54.25 - 82.26)	47/61; 77.05 (64.5 - 86.85)	32/33; 96.97 (84.24 - 99.92)	79/94; 84.04 (75.05 - 90.78)	0.87 (*P*<0.001)
Expert 2 (n=135)						
CRM criteria	31/51; 60.78 (46.11 - 74.16)	25/84; 29.76 (20.27 - 40.73)	31/90; 34.44 (24.74 - 45.2)	25/45; 55.56 (40 - 70.36)	56/135; 41.48 (33.07 - 50.27)	0.45
Mendoza criteria	39/51; 76.47 (62.51 - 87.21)	17/84; 20.24 (12.25 - 30.41)	39/106; 36.79 (27.63 - 46.71)	17/29; 58.62 (38.94 - 76.48)	56/135; 41.48 (33.07 - 50.27)	0.48
AI	50/51; 98.04 (89.55 - 99.95)	57/84; 67.86 (56.78 - 77.64)	50/77; 64.94 (53.22 - 75.47)	57/58; 98.28 (90.76 - 99.96)	107/135; 79.26 (71.44 - 85.75)	0.82 (*P*<0.001)
Expert 3 (n=136)						
CRM criteria	30/51; 58.82 (44.17 - 72.42)	34/85; 40 (29.52 - 51.2)	30/81; 37.04 (26.56 - 48.49)	34/55; 61.82 (47.73 - 74.59)	64/136; 47.06 (38.45 - 55.8)	0.45
Mendoza criteria	40/51; 78.43 (64.68 - 88.71)	13/85; 15.29 (8.4 - 24.73)	40/112; 35.71 (26.88 - 45.32)	13/24; 54.17 (32.82 - 74.45)	53/136; 38.97 (30.73 - 47.7)	0.50
AI	50/51; 98.04 (89.55 - 99.95)	58/85; 68.24 (57.24 - 77.92)	50/ 77; 64.94 (53.22 - 75.47)	58/59; 98.31 (90.91 - 99.96)	108/136; 79.41 (71.64 - 85.86)	0.82 (*P*<0.001)
Expert 4 (n=136)						
CRM criteria	62/84; 73.81 (63.07 - 82.8)	16/52; 30.77 (18.72 - 45.1)	62/98; 63.27 (52.93 - 72.78)	16/38; 42.11 (26.31 - 59.18)	78/136; 57.35 (48.59 - 65.79)	0.56
Mendoza criteria	83/84; 98.81 (93.54 - 99.97)	1/52; 1.92 (0.05 - 10.26)	83/134; 61.94 (53.16 - 70.18)	1/2; 50 (1.26 - 98.74)	84/136; 61.76 (53.05 - 69.96)	0.56
AI	76/84; 90.48 (82.09 - 95.8)	39/52; 75 (61.05 - 85.97)	76/89; 85.39 (76.32 - 91.99)	39/47; 82.98 (69.19 - 92.35)	115/136; 84.56 (77.37 - 90.18)	0.84 (*P*<0.001)

DSOC AI software achieved statistically significant accuracy values ($p < 0.001$) for neoplastic diagnosis when compared with expert endoscopists.

≥ 90% sensitivity
≥ 68% specificity
≥ 65% positive and
≥ 83% negative predictive values

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- The proposed AI model accurately recognized between neoplastic and non-neoplastic bile duct lesions with good accuracy, matching the experts in DSOC and may even significantly overcome them.
- AI model may aid in improving less experienced endoscopists by shortening learning curves time, while attaining accurate biliary lesion recognition skills.
- Further prospective live studies to evaluate the role of AI to target biopsies are encouraged.

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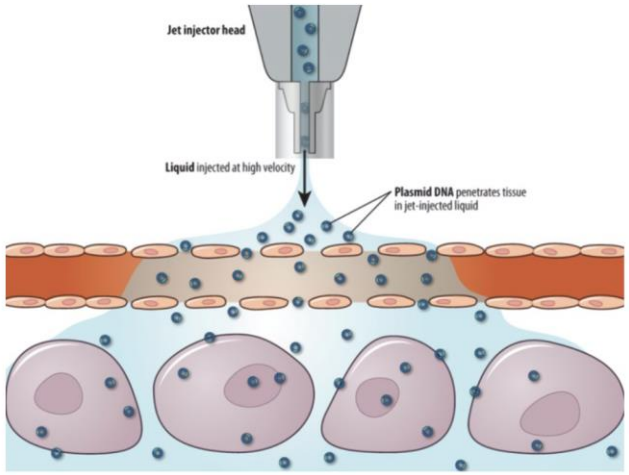
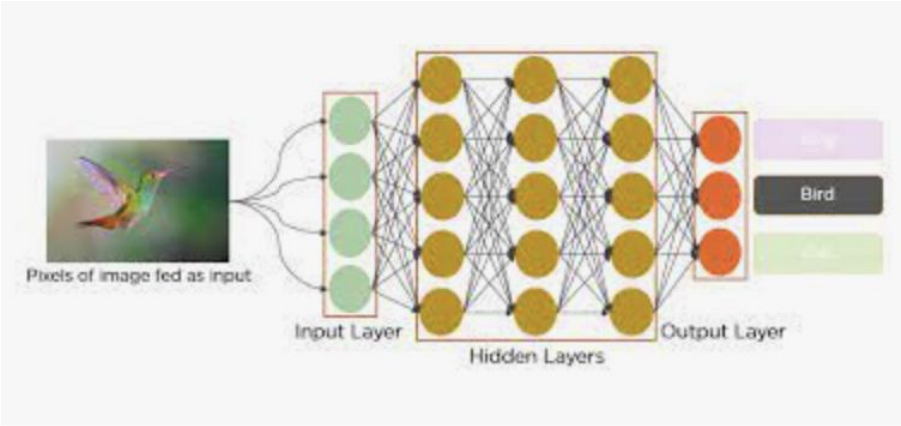
THANK YOU





Convolutional Neural Networks