

Preliminary Observations of A Randomized, 2-Way Crossover Study Comparing the Endoscopic Pancreatic Function Test (ePFT) with Secretin for Exocrine Pancreas Function With and Without Meperidine / Midazolam Sedation in Normal Subjects. Darwin L. Conwell, Ed Purich*, Gregory Zuccaro, Seymor Fein*, Frederick VanLente, John Vargo, John Dumot, Patricia Trolli and Julie Tsirambidis. *The Pancreas Clinic, Section of Endoscopy, Department of Gastroenterology, Cleveland Clinic Foundation, Cleveland, Ohio and ChiRhoClin, Inc. Burtonsville, MD**

Background: The traditional (Dreiling tube) methods for collecting pancreatic juice for function testing are no longer available. We have developed a purely endoscopic collection method for the assessment of pancreatic secretory function. (*Gastrointest Endosc* 2003; 57:37-40). The effects of conscious sedation and analgesia medications on pancreatic secretion are not currently known. A prospective trial has been developed to assess the effects (synergistic or antagonistic) of combining opiates and benzodiazepines as utilized in endoscopic procedures on pancreatic secretion.

Aims: To study the effects of medications used for conscious sedation in upper endoscopy on pancreatic function in a prospective, randomized trial.

Methods: Healthy subjects underwent a one hour secretin stimulated ePFT randomized by computer to one of two treatments (A-sedation, B-unsedated) in period 1 and crossed-over to the other treatment in period 2 with a minimal interval of 7 days. Sedation dosage was determined from a previously published dosing nomogram. Synthetic porcine secretin (ChiRhoClin, Inc.) was used as the pancreatic stimulant. An ultrathin 6 mm upper endoscope (Olympus GIF-XP 160) was used for duodenal aspiration to improve patient tolerance. Fluid samples were aspirated via the endoscope every 5 minutes for one hour and immediately sent (< 15 minutes) on ice to our hospital laboratory for measurement of bicarbonate.

Results: A total of 6/16 healthy volunteers (1 male and 5 female) have been randomized into the prospective trial to date. Preliminary observations are reported. The mean peak bicarbonate for sedated (n=3) versus non-sedated (n=3) study participants was 108 (SD \pm 7) meq/L and 103 (SD \pm 16) meq/L respectively. Chart shows the bicarbonate secretory curve for both groups. One study participant has completed both sedated and unsedated treatment arms. Mean peak bicarbonate for this subject was 93 meq/L sedated and 102 meq/L unsedated. There were no complications or episodes of pancreatitis.

Conclusions: 1) Conscious sedation with meperidine / midazolam at doses used in standard upper endoscopy do not appear to effect the response of the exocrine pancreas to stimulation with secretin. 2) Study subjects are currently being enrolled to complete this prospective trial.

