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Effect of Udenafil on the Prevention of Post-ERCP Pancreatitis (PEP): Prospective, Randomized, Double-Blinded, Placebo-Controlled, Multicenter Study
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Background: Pancreatitis is the most common complication of endoscopic retrograde cholangiopancreatography (ERCP). Obstruction of pancreatic outflow may arise from mechanical injury to the papilla and pancreatic sphincter, and pancreatic sphincter hypertension. A recent study showed phosphodiesterase type-5 (PDE-5) inhibitor reduced sphincter of Oddi (SO) motility. PDE-5 inhibitor may decrease SO tone, allow easy cannulation, and reduce the incidence of PEP. Methods: After initial screening, 278 enrolled patients were randomized and stratified by age and sex to Udenafil group (n=137) and Placebo group (n=141). Udenafil (Zydexa®, Dong-A Pharmaceutical Co, Korea) or Placebo was given 2h before ERCP and all patients were prospectively evaluated for the development of pancreatitis until 72 h after ERCP. The incidence of PEP and factors associated with PEP were analyzed. Results: Demographic features, indication for ERCP and therapeutic procedures were similar in 2 groups. The overall incidence of pancreatitis was 7.9%. There was no difference in the incidence of PEP (8.0% vs. 7.4%, p=0.940) and SO pressure (p=0.971) between the Udenafil and Placebo groups. On univariate analysis, age ≤ 40 years, suspected SO and complete pancreatic opacification was associated with PEP. On multivariate analysis, age ≤ 40 years, suspected SO and complete pancreatic opacification were independently associated with PEP. There was only mild udenafil-related complications including flushing (n=3) and headache (n=5). Conclusions: Phosphodiesterase-5 inhibitor, Udenafil, was not effective in the prevention of PEP.

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A Prospective Double Blind Randomised Controlled Trial of Carbon Dioxide Versus Air Insufflation During ERCP: Is It Worth the Pain?
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Introduction: Abdominal pain after ERCP is a common occurrence which often poses diagnostic uncertainty. Carbon dioxide (CO2) insufflation during colonoscopy has been shown to reduce post procedural discomfort. We conducted a randomised, double-blind controlled trial to compare the severity of post-ERCP pain in patients receiving CO2 versus air insufflation. Methods: Patients presenting for ERCP were enrolled consecutively, aiming for a sample size of 88 patients (44 patients per treatment arm, 80% power, alpha=0.05). The primary endpoint was pain. Patients were randomized to either CO2 or air insufflation. Pain was measured using a Visual Analogue Scale (VAS: 0-10). Results: We report the interim findings of 61 patients (43 women, mean age: 58.4 years, 34 randomized to CO2) who have completed the study thus far. Patient demographics, indication for ERCP, in/outpatient status, procedure duration, capnography readings, sedation dose and use of post-procedural analgesia were similar in both groups. Pain was more severe pre-procedure in the group receiving air insufflation compared to CO2 (1.51 vs. 0.38, p=0.02), however on discharge there was no difference between both groups (0.37 vs. 0.38, p=0.97) respectively. Pain had improved significantly after ERCP in the group receiving air insufflation (1.51 to 0.57, p=0.01), but not in the CO2 group (0.38 to 0.38, p=0.50). This finding may have been compounded by the higher pre-procedural pain experienced in the air insufflation group. Conclusions: Our preliminary results suggest that there was no added benefit of insufflating CO2 during ERCP when compared to air. We postulate that these findings are contrary to promising data of using CO2 during withdrawal in colonoscopy. Furthermore, once the ampulla is reached the proceduralist generally refrains from insufflating the duodenum further. This is in contrast to withdrawal in colonoscopy where insufflation is generally necessary to avoid missed lesions.

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Ex-Vivo Fragmentation of Biliary Stones Using Holmium-YAG Laser
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BACKGROUND: Holmium-YAG laser lithotripsy has been shown to be an effective therapy for refractory biliary duct stones. Prior studies have shown Holmium-YAG laser to be safe when used in short bursts (<5 sec) at power settings ranging from 8W to 12W. The aim of this study was to determine the optimal power settings and identify any factors limiting the ability to fragment stones within the previously determined safe power settings. METHODS: 73 biliary stones ranging in size from 0.6 to 5.3cm were retrieved from cholecystectomy cases. Individual stones were measured and their constituency characterized as cholesterol, pigmented or mixed stones. A SlimLine Holmium-YAG laser probe (Lumenis, Santa Clara, CA) was placed in contact with individual stones in a water medium and activated. The power settings used ranged from 8W to 12W and were accomplished using various combinations of frequency (Hz) and joules (J). The laser was activated in 5 second bursts until stone fragmentation was achieved or for a maximum of 60 seconds. Fragmentation was defined on a scale of 1-4: (1) Complete fragmentation without drilling; (2) Slight drilling with fragmentation; (3) Cleavage into 2 pieces after heavy drilling effect; (4) Complete drilling without fragmentation. Success in fragmentation was defined as reaching a score of 1,2, or 3 on the above scale. ANOVA with a covariance analysis of the following variables: stone constituency and size, laser wattage (W) and frequency (Hz) was performed to assess predictive factors for stone fragmentation. RESULTS: Statistical analysis revealed laser wattage (W) and stone constituency to be non-significant variables in stone fragmentation. There was a significant negative association between stone size (p<0.05) and laser frequency using 5-20Hz (p<0.05) to stone fragmentation. Fragmentation of stones diminished with increasing stone size and laser frequency. Figure 1 depicts the relationship between stone fragmentation and stone size at frequency (5Hz and 20Hz). CONCLUSIONS: Holmium-YAG laser is an effective tool for the fragmentation of stones less than 2cm. Current recommended power settings appear to cause increased drilling effects rather than fragmentation in the larger stones. Further studies with revised settings using higher power settings with low frequency are required to determine the efficacy of Holmium-YAG laser lithotripsy in refractory stones greater than ≈ 2cm.

Figure 1

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