Comparison of Outcomes in Patients Undergoing Endoscopic Retrograde Cholangiopancreatoscopy (ERCP) Using Duodenoscope with Single-use Distal Cover and Conventional Reusable Duodenoscope: A Randomized Controlled Trial

Study Protocol and Statistical Analysis Plan

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Background and Rationale

Over the past decade, multiple outbreaks of infections due to drug-resistant organisms have been traced to contaminated conventional reusable duodenoscopes. While lapses in reprocessing protocols may contribute, the inherent design of reusable duodenoscopes has also been implicated.

Despite enhanced reprocessing guidelines issued by the FDA, persistent contamination remains a concern. Studies report that **3–5%** of duodenoscopes continue to yield positive cultures even after reprocessing. In response, duodenoscope manufacturers have introduced models with **disposable distal end caps (DDEC)** intended to improve reprocessing efficacy and reduce infection risk.

However, these DDEC duodenoscopes have been linked with specific adverse events such as detachment of the distal cap, rigidity, scope fracture, contamination, imaging issues, and functional failure. To date, **no large-scale or long-term comparative study** has evaluated procedure success and complication rates between DDEC and **conventional reusable duodenoscopes (CRD)**.

Study Objective

To compare:

- Procedure-related complication rates (primary outcome)
- Procedure success rates and technical performance characteristics (secondary outcomes)

in patients undergoing ERCP with either DDEC or CRD.

Study Design

- **Design Type:** Prospective, randomized controlled trial
- **Sample Size:** 600 patients (300 per group)
- **Setting:** Stanford Hospital Endoscopy Unit
- **Randomization:** Block randomization with equal allocation
- **Follow-Up:** Phone calls at 1 week, 1 month, and 3 months to assess delayed complications

Study Population

Inclusion Criteria:

1. Age > 18 years
2. Undergoing ERCP for biliary or pancreatic indications

Exclusion Criteria:

1. Vulnerable groups (e.g., pregnant women)

2. Inability to provide informed consent
3. Known cholangitis
4. Known infection with CRE or other MDRO
5. Surgically altered anatomy (except Billroth I)

Study Interventions

Participants will be randomized to undergo ERCP using one of the following duodenoscopes:

- **Group A:** Duodenoscope with Disposable Distal End Cap (DDEC)
- **Group B:** Conventional Reusable Duodenoscope (CRD)

Both scopes are **FDA-approved** and considered standard of care.

Outcome Measures

The primary outcome measured in this study is the total patient complication rate, which includes cap detachment, severe mucosal injuries, post-ERCP pancreatitis, post-sphincterotomy bleeding, perforation, cholangitis, abdominal pain, fever, and procedure-related death. Secondary outcomes include the overall procedure success rate; successful intubation rates at key anatomical checkpoints (oropharyngeal/esophageal, gastroesophageal junction, and pyloric/duodenal regions); occurrence of suboptimal papillary positioning; total procedure time; cannulation time; fluoroscopy time and total radiation dose; use of advanced cannulation techniques; inadvertent duct cannulation; and need for crossover to an alternate duodenoscope due to technical failure or procedural difficulty.

The initial sample size was determined based on an expected complication rate of 7% in the CRD group and 14% in the DDEC group. Assuming a 1:1 randomization, alpha error of 0.05, and study power of 80%, a total of 600 patients (300 per group) were required. Interim analyses were conducted during the study to assess efficacy and futility using conditional power analysis calculated with the frequentist Z-statistic method.

- **Maneuverability:** Scored on a validated 5-point scale
  (1 = Easy; 5 = Unable to complete the required maneuver)
- **Mechanical Characteristics:**
  Scope stiffness, air-water button functionality, elevator efficiency, and hand strain (each scored on a 5-point scale)
- **Imaging Characteristics:**
  Image quality and image stability (each scored on a 5-point scale)

Data Collection and Analysis

- **Data Collection:**
  Conducted prospectively by evaluators during and after the procedure
- **Statistical Analysis:**
  - Categorical variables compared using chi-square or Fisher's exact tests, as appropriate
  - Analysis conducted using the **intention-to-treat** approach
  - **Software:**
    - *IBM SPSS Statistics* v29.0.2.0 (IBM Corp, Armonk, NY)
    - *R* v4.2.2 for conditional power analysis (R Foundation for Statistical Computing, Vienna, Austria)

Ethical Considerations

- IRB approval will be obtained prior to initiation
- Written informed consent will be obtained from all participants
- Data will be stored securely in compliance with HIPAA regulations
- Adverse events will be monitored and reported in accordance with institutional guidelines

Figure 1: Study flow diagram