Title: Prospective Evaluation of Winged Biliary Stent Patency in Patients With Benign Biliary Obstruction

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Aim:

The primary aim of this study is to prospectively evaluate the patency rate of the WS up to 90 days in 100 patients with biliary obstruction due to stones or benign strictures.

Patient Criteria:

Inclusion criteria:

1) All patients age 18 or older referred for ERCP for biliary obstruction from stones or benign strictures that have been confirmed based on clinical, laboratory and imaging findings, with an indication for plastic stent placement.
2) Expected patient survival of at least 90 days
3) High likelihood of patient follow-up
4) Patient is able to give a written informed consent
5) Patient is willing and able to comply with the study procedures.

Exclusion criteria:

1) Patients with cholangitis
2) Patients with bile leak
3) Pregnant patients
4) Patients with any contraindication to endoscopic procedure
5) Participation in another investigational study that may directly or indirectly affect the results of this study within 30 days prior to the initial visit
6) Patients with malignant biliary strictures

Methods:

1) Patients that meet all the inclusion criteria and have none of the exclusion criteria will be invited to participate in the study.

2) Initial visit:
- Written informed consent will be obtained
- Complete history and physical will be performed and the patients baseline liver function
tests and imaging results will be assessed and noted in the case report form.
- Patient's gender, date of birth, concomitant medications will be noted.

3) Procedure:
Patients will then be scheduled for the ERCP procedure with wing biliary stent placement. They will undergo the ERCP as standard of care and the wing biliary stent will be placed for decompression of the obstructed biliary system in situations where

stenting is standard of care.

4) Bloodwork:
Patients will undergo bloodwork (total and direct bilirubin, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase) one week after the procedure. The degree of drop in bilirubin will also be noted. The patients will be then have these labs drawn again at designated time points for this study.

5) Telephone calls:
The patients will be called on the telephone at designated time points after the procedure to monitor their clinical status. Patients and family members will be given a contact number to call us immediately if they develop any signs of biliary obstruction such as fever, abdominal pain, jaundice, dark urine or light stools. They will also be instructed to come to the emergency room should they develop fevers.

6) Stent removal:
At the end of 90 days from the stent placement patients will return for a repeat ERCP for stent removal as the standard of care and further endo-therapy as indicated.

7) Stent patency will be calculated from the time of stent insertion up to the end of 90 days. The stent patency rate at 90 days will be the proportion of stents placed that do not occlude over this time period. Stent occlusion will be defined as biochemical or clinical evidence of obstructive jaundice.

8) All the continuous and outcome variables (stent obstruction) will be statistically analyzed and stent malfunction rates will be analyzed for the WS across the various indications.

Variables to be monitored Pre or during procedure:

1. Baseline clinical symptoms: jaundice, abdominal pain, fever.
2. Biochemical parameters: total and direct bilirubin, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase.
3. Technical success in stent placement
4. Any immediate procedure related complications such as perforation, bleeding or pancreatitis.

Variables to be monitored Post procedure:

1. Stent patency rates for the WS.
2. Stent migration proximal or distal, leading to repeat ERCP
3. Any delayed procedure related complications such as pancreatitis, cholangitis and/or jaundice.

Statistical Analysis Plan

Stent patency will be assessed based on the above characteristics utilizing standard statistical techniques (mean, standard deviation) with primary outcome measure of stent patency.

Additional statistical measures for sensitivity, to adjust for covariates and compare sample groups are not relevant, as this is a study focused on defined primary outcome measures in a single population.