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INTRALUMINAL BYPASS DEVICE FOR THE REPLACEMENT OF DIVERTING STOMA: RESULTS FROM FIRST PROSPECTIVE CLINICAL TRIAL IN 20 PATIENTS.

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Purpose/Background: the Cologuard CG-100 is a novel intraluminal bypass device designed to improve the clinical outcomes associated with low colorectal anastomotic leak (FiG 1). The device is inserting trans-anally anchored to the colon above the anastomosis, and deployed intra-luminally to cover the anastomosis from within. Previous study in a porcine model showed that the device efficiently reduced contact between fecal content and low colorectal anastomosis and was easily deployed and extracted. The purpose of this study was to evaluate the safety and performance of the device in patients under- going colorectal anastomosis.

Methods/Interventions: twenty consecutive patients underwent colorectal anastomosis with insertion of the Cologuard CG-100 device. After 10 days, when the risk for leakage was reduced, the anastomosis integrity was examined by contrast which was injected through a catheter between the silicon sheath and the colonic mucosa and the device was pulled out. Data regarding demographics, surgical details, and 30 day post-operative complication were collected prospectively. Measure of the device performance was evaluated. Physician and patients' satisfaction were evaluated by questionnaires.

Results/Outcome(s): 20 patients underwent colorectal surgery using the new CG-100 device, 11 males (55%) with median age of 65.1 ± 9.7. indication for surgery was colorectal cancer and the median distance of the anastomosis from the anal verge was 7.4±4.5 cm. Preoperative neo adjuvant radiation was given in 30% of the patients. majority of the procedures were performed in a laparoscopic approach with median surgery duration of 172 minutes and the median application time of the CG-100 device was 10 minutes. in 7 cases (35%) a diverting stoma was performed on top of using the CG-100 device.

Application and removal of the device was performed uneventfully in all 20 cases. 6 patients (30%) experienced post-operative morbidity (2 anastomotic leakages, 1 wound infection, 1 abdominal collection and 1 patient with minor rectal bleeding post removal of the device). the device required minimum, if any, training to learn how to apply. the overall complexity of the device was intuitive. the device was easily deployed and extracted. Patients did not report major discomfort caused by the sheath. A minimal incontinence for loose stool was observed as long as the sheath was in situ.

Conclusions/Discussion: the CG-100 reduces the contact of fecal stream with the anastomotic site. The device is easy to install with no major complications and may replace the usage of ileostomy in order to protect the anastomotic site. A study with a larger sample size is ongoing to further investigate the safety and performance of the CG-100 device.