

Use Of The Dilumen™ Double Balloon Endoscopic Platform In Complex Colon ESD Results In Faster ESD And Faster Endoscopic Suturing Device Insertion For Sutured Defect

AUTHORS:

Stavropoulos, Stavros N.; Ly, Erin; Nithyanand, Sagarika; Khodorskiy, Dmitriy O.; Peller, Hallie; Modayil, Rani J.



INSTITUTIONS (ALL):

1. NYU Winthrop, Mineola, NY, United States.

BACKGROUND/AIM:

Poor endoscope operability is an important predictor of difficulty in colon ESD. A newly developed double balloon device (DiLumen, Lumendi) purports to address poor endoscope operability (including looping of the endoscope in the sigmoid and transverse colon and difficult access to certain locations such as the flexures and IC valve) by offering improved visualization, scope stabilization, and tissue manipulation. We present data from the 1st US pilot study of this device aiming to evaluate the clinical performance of this device in colonic

ESD.Methods:

Between May 2017- March 2018, 27 patients with complex colon lesions underwent 30 resections with the device. The procedures included 3 EFTRs, 4 EMRs, and 23 ESDs. ESDs were in the following locations: sigmoid 3, TC 2, Hepatic flexure 4, Ascending Colon 8, Cecum 4, Ascending colon 8, IC valve 2. After exclusion of 4 training ESDs, 19 ESDs with the device were propensity-score matched to 19 conventional ESDs extracted from our prospective database. The two most recent years were used (2016 and 2017) to exclude a learning curve effect (the operator had performed over 300 ESDs prior to 2016). Age/sex, lesion location, specimen size, and significant prior lesion manipulation were covariates matched (see Table 1). Dissection time/speed, R0 resection rate and adverse event rates were compared between the two groups. A secondary endpoint was assessment of the degree to which this device facilitates insertion of an endoscopic suturing apparatus loaded on a therapeutic gastroscope which can be difficult to insert beyond the rectum. 5 suturing cases aided by the DiLumen device were independently case-matched based on location to 5 cases in which the device was not used to aid insertion (Table 2). Insertion time for the endoscopic suturing apparatus to the level of the ESD defect was compared between the two groups. Results (see Table 1 and 2): Use of the DiLumen device increased ESD dissection speed by 4.7 cm/hr. (52%, $p=0.098$) and reduced insertion time for the endoscopic suturing apparatus by 8.6 minutes (84%, $p=0.003$). R0 resection rate (89.5% in both groups) and adverse event rate (3 vs 2 mild/moderate AEs in the DiLumen and control group respectively) was favorable and similar in both groups.

Conclusions:

Our study is the first to present feasibility data and comparative data on the use of a novel double balloon platform for colonic ESD. Our data support the potential of this platform to increase ESD speed (which may improve adoption of colorectal ESD in the US) and facilitate colonic insertion of an endoscopic suturing device. Suturing of ESD defects has been previously reported to decrease hospital stay and may decrease the risk of delayed bleeding and perforation after colorectal ESD. Further studies are necessary to confirm these promising results.

TABLE 1

| | | Control (N=19) | Lumendi (N=19) | p-value |
|--|-----|----------------|----------------|---------|
| COVARIATES MATCHED | | | | |
| Sex | F | 7 | 6 | 1.000 |
| | M | 12 | 13 | |
| Hard Location of Lesion | No | 7 | 10 | 0.515 |
| | Yes | 12 | 9 | |
| Sig. Prior Manipulation | No | 10 | 8 | 0.746 |
| | Yes | 9 | 11 | |
| Lesion Area (cm²) | | 8.725 ± 8.103 | 11.454 ± 6.843 | 0.149 |
| Age | | 72.9 ± 4.2 | 70.7 ± 10.0 | 0.46 |
| OUTCOMES ASSESSED | | | | |
| Speed (cm²/hr) | | 9.06 | 13.74 | 0.098 |
| R0 Resection | | 17 (89.5%) | 17 (89.5%) | NS |
| ADVERSE EVENTS (all mild/moderate; prolonged LOS due to comorbidities; no surgery, IR, other intervention) | | 3 | 2 | NS |
| Mean LOS | | 2.8 | 1.5 | 0.153 |

TABLE 2

| Sutured Defect Closure Case Match | | Control (N=5) | Lumendi (N=5) | p-value |
|--|---------|-------------------------|-------------------------|---------|
| Location | Cecum | 3 | 3 | 1.000 |
| | Sigmoid | 1 | 1 | |
| | TC | 1 | 1 | |
| Sex | F | 0 | 0 | 1.000 |
| | M | 5 | 5 | |
| Age | | 61.6 ± 8.4 | 69.6 ± 6.4 | 0.131 |
| Insertion Time | | 8.8 ± 2.8 Median = 9 | 1.6 ± 0.5 Median = 2 | 0.004 |



253 Post Road West, Westport, CT 06880
 Tel: (203) 463-2669 Fax: (203) 557-0459
Lumendi.com