ClutchCutter® in Clinical Studies

Published in Gastrointestinal Endoscopy, Vol. 91, Issue 6, AB419–AB420:

Safety and Feasibility of Same Day Discharge

Following Esophageal Endoscopic Submucosal Dissection

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Background: Endoscopic submucosal dissection (ESD) is an endoscopic resection technique used for the treatment of early luminal gastrointestinal cancer. ESD has become standard of care in East Asia, where it results in a multi-day hospital admission for observation. Similarly, in the US, standard of care usually involves at least an overnight hospital stay. There is, however, limited data regarding practice in Western hospitals. AIM: To evaluate the safety and feasibility of same day discharge (SDD) following esophageal ESD.

Methods: This is a retrospective cohort study of adults who underwent esophageal ESDwith a ClutchCutter device (DP2618DT; Fujifilm Corporation, Tokyo, Japan) at Mayo Clinic (Rochester, MN) from 2017-2019. The primary end point was post-procedural complications within 7 d of ESD, including need for physician phone call, Emergency Department visit, rehospitalization, and medical or endoscopic intervention.

Results: Of 96 patients (75% male, mean age 70±10.3 y) undergoing a total of 140 ESDs, 85 (60.7%) were SDDs vs 55 (39.3%) who were admitted. Of the 55 admits, 53 (96.4%) were discharged within 24 h, while 2 (3.6%) were admitted 2-3 d due to hypertensive urgency and TIA unrelated to ESD. SDD patients vs admits were similar in mean age (69.2 vs 71.4 y; p0.22) and sex (75.3% vs 71.4%; p0.84). However, admits were more likely to have a history of antiplatelet/anticoagulant (AP/AC) use (56.4% vs 34.1%; p0.01) and higher mean ASA physical status score (3.2 vs 2.9; p0.007). Admits had larger resections (28.6 vs 20.1 mm; p<0.0001) with longer durations (103.4 vs 62 min; p<0.0001). No difference in fibrosis was noted (12.7% vs 17.6%; p0.48). Among SDDs, no intraprocedural or postprocedural complications were seen. Among admits, 1 (1.8% vs 0%; p0.39) experienced intraprocedural bleeding requiring endoscopic intervention, 1 required transfusion prior to discharge within 24 h of ESD (1.8% vs 0%; p0.39), and 1 required rehospitalization and endoscopic intervention within 7 d to address an active bleed along the resection margin (1.8% vs 0%; p0.39). Overall, associated pathology was as follows: 5% had normal findings; 13.6% non-dysplastic Barrett's esophagus (BE); 2.9% BE with indefinite dysplasia; 13.6% BE with low grade dysplasia; 20.7% BE with high grade dysplasia; 27.9% esophageal adenocarcinoma; 6.4% squamous cell carcinoma; and 10.0% had other findings, such as squamous dysplasia. Patients were on AP/AC therapy leading up to 42.9% of the procedures, including 5.7% on high dose aspirin, 2.9% clopidogrel, 6.4% warfarin, and 8.6% direct oral anticoagulants.

Conclusion: SDD following esophageal ESD is safe and feasible. Additional prospective data will help establish more uniform criteria for low risk patients. Based on our experience, SDD can be considered in patients who are fit with ASA £2 and undergo smaller resections off AP/AC therapy.

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FUJIFILM SUMMARY

Fujifilm offers various tools to assist in Endoscopic Submucosal Dissection (ESD). This retrospective cohort study selected those who underwent esophageal ESD with a ClutchCutter device from Fujifilm.

Key Takeaways:

- 1. In a study using Fujifilm's ClutchCutter, same day discharge of esophageal ESD patients was shown to be safe and feasible.
 - a. In 140 ESDs, 85 (60.7%) patients were discharged the same day vs. 55 (39.3%) that were admitted.
 - b. Of the 55 admitted, 53 (96.4%) patients were discharged within 24 hours vs. 2 (3.6%) that were discharged after 2-3 days.

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