ELEVIEW™ CASE STUDY: LATERALLY SPREADING LESION

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Colorectal cancer develops from changes in benign polyps in the lining of the gastrointestinal tract.[1] The Paris classification system divides colorectal polyps into 2 broad categories based on their morphology: protruded and flat. The protruded lesions include type 0-Ip (pedunculated) and type 0-Is (sessile). The flat lesions include type 0-IIa (flat elevated, height less than 2.5 mm), type 0-IIb (completely flat), type 0-IIc (depressed), and type 0-III (excavated).[2] Flat lesions usually require submucosal injection before resection.[3]

Endoscopic mucosal resection (EMR) was developed for the removal of benign and early malignant lesions confined to the superficial layers (mucosa and submucosa) of the gastrointestinal tract.[4] In EMR, a submucosal injection creates a cushion for the polyp, which can then be snared either en bloc or piecemeal.[3]

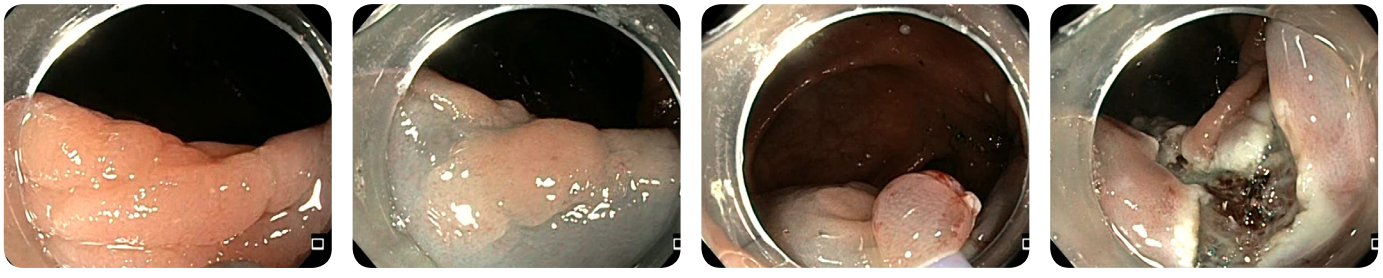
The advantage of en bloc removal is that it allows for full histological assessment of the complete resection.[5]

Eleview™ is a ready-to-use, sterile, submucosal injection agent that has been 510(k) cleared as a medical device for use by the US Food and Drug Administration (FDA).[6] It is designed to provide a submucosal cushion of optimal height and duration, creating a long-lasting cushion that lasts for up to 45 minutes.[6,7] It has been premixed with methylene blue to create a contrast with the natural color of the mucosa, allowing the endoscopist to perceive the exact position of the cutting device. This helps to visualize the margins of the target lesion and to decrease risk of damage to the muscular layer, which could lead to perforation.[6,7] Eleview™ is also compatible with most common endoscopic devices.[6]

Eleview™ Used in EMR With a Lateral Spreading Lesion:

- Description: Laterally spreading lesion, granular type, IIa, NICE classification type 2, ~3 cm in size
- Location: Ascending colon
- Procedure: Removed completely by submucosal injection of Eleview™ in a piecemeal fashion
  - A total of 5 mL of Eleview™ was used for this specific lesion (half of a 10mL/ampoule)

PRESENTATION | **POST-INJECTION** | **RESECTION** | **POST-RESECTION**



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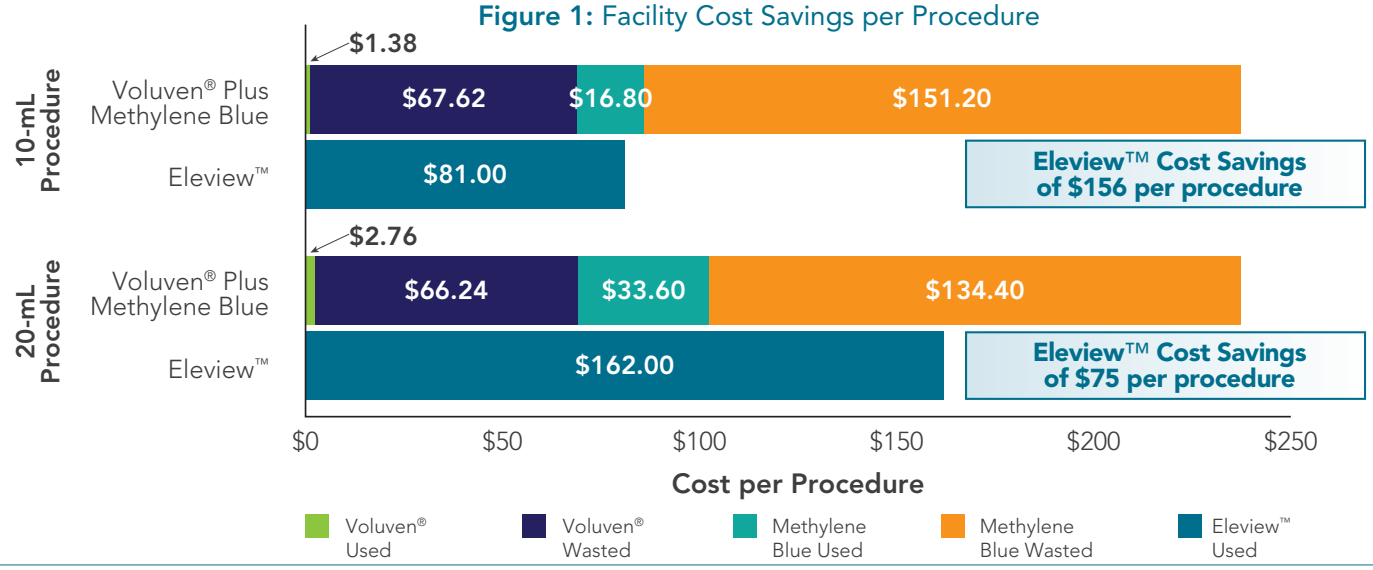
Eleview™

Economic Case Study: Eleview™ vs Voluven® Plus Methylene Blue

The goal of this economic case study is to assess the cost of Eleview™ vs Voluven® plus methylene blue, our standard of care for submucosal injection agents. In our practice, we routinely use 10 mL to 20 mL of the submucosal injection agent Voluven® plus methylene blue when we inject a patient for EMR. However, the 10 mL to 20 mL of Voluven® plus methylene blue used does not represent the entire cost of the procedure, as the unused portion of the submucosal injection agent must be discarded to ensure sterility.

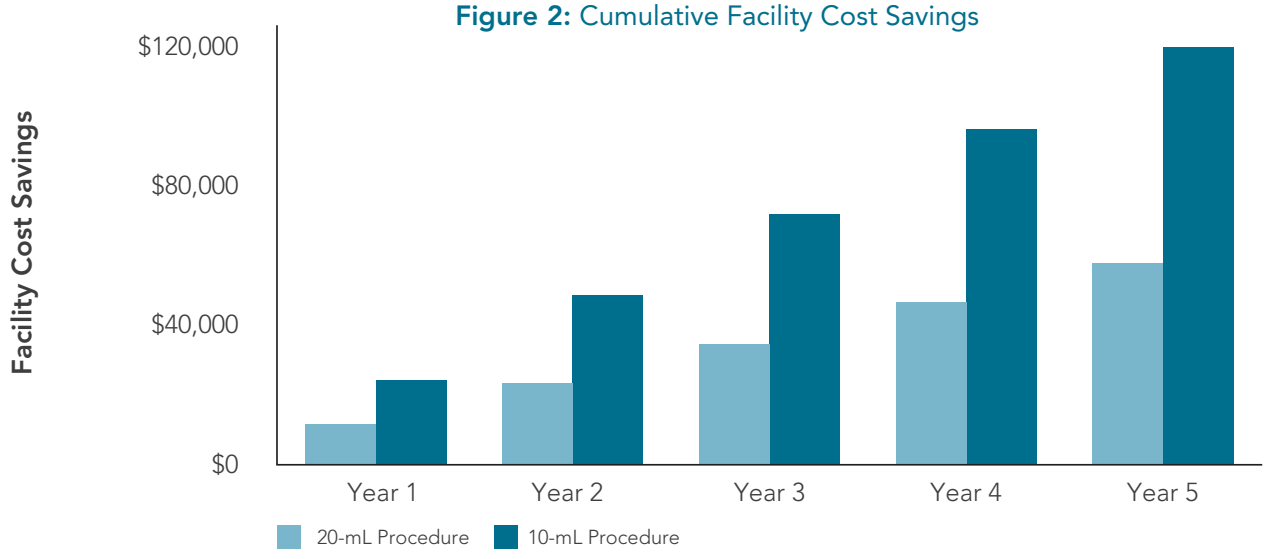
Voluven® costs $69 per 500-mL bag, while methylene blue costs $168 per 10-mL vial. Eleview™ is packaged in 10 mL single-use vials, 5 to a box, and costs $81 per vial. In our economic model, shown in Figure 1, the cost per procedure is calculated based on the amount used per procedure (either 10 mL or 20 mL), plus the cost of the unused portion (waste). In this scenario, using Eleview™ will save our practice $75 to $156 per procedure **(Figure 1)***.

Figure 1: Facility Cost Savings per Procedure



In our practice, we perform approximately 150 endoscopic resections requiring submucosal injection per year. On an annual basis, using Eleview™ results in a facility cost savings that ranges from $11,250 to $23,400 per year. This adds up to a cumulative cost savings of $56,250 to $117,000 over a 5-year period **(Figure 2)**.†

Figure 2: Cumulative Facility Cost Savings



It should be noted that this economic case study highlights direct supply cost comparisons which show Eleview™ as favorable. What is not measured in this analysis are the additional, indirect costs associated with the creation of a custom submucosal injection agent such as Voluven® plus methylene blue. Those indirect cost drivers include additional procedure time to mix custom agent, additional cost of anesthesia time, decrease in procedural throughput, and burden on pharmacy staff to choose and deliver components to the GI clinic and/or compounding services.

*All numbers are based on nationally available costs.

†Cumulative cost savings are hypothetical based on estimated procedural volume requiring the use of a submucosal injection agent.

1. Simon K. Colorectal cancer development and advances in screening. *Clin Interv Aging*. 2016;11:967-976. **2.** Participants in the Paris Workshop. The Paris endoscopic classification of superficial neoplastic lesions: esophagus, stomach, and colon. *Gastrointest Endosc*. 2003;58(6)(suppl):S3-S43. **3.** Fyock CJ, Draganov PV. Colonoscopic polypectomy and associated techniques. *World J Gastroenterol*. 2010;16(29):3630-3637. **4.** Hwang JH, Konda V, Abu Dayyeh BK, et al; ASGE Technology Committee. Endoscopic mucosal resection. *Gastrointest Endosc*. 2015;82(2):215-226. **5.** Bujanda L, Cosme A, Gil I, Arenas-Mirave JI. Malignant colorectal polyps. *World J Gastroenterol*. 2010;16(25):3103-3111. **6.** Eleview™ Instructions for Use. Aries Pharmaceuticals, Inc. 2017. **7.** Data on file. Aries Pharmaceuticals, Inc.