

Routine Prophylactic Clip Closure is Cost Saving After Endoscopic Resection of Large Colon Polyps in a Medicare Population

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SHORT TITLE: Budget impact analysis: clip closure after resecting large colon polyps

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ABBREVIATIONS: EMR (endoscopic mucosal resection)

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INTRODUCTION

Post-procedure bleeding remains the most common adverse event associated with endoscopic mucosal resection (EMR) of large polyps.¹ Sequential placement of multiple endoclips can be utilized to completely close the post-resection defect following endoscopic removal of a large colon polyp. Recently, three multicenter, randomized controlled trials found that prophylactic clip closure reduces the risk of post-procedure bleeding after endoscopic resection of large colon polyps ≥ 20 mm in diameter.²⁻⁴ While the clinical benefit of prophylactic clip closure in this setting is becoming more clear, deploying several endoclips often remains cost-prohibitive to implement in routine practice as endoclips are not presently reimbursed by payers.

Budget impact analysis is an important tool to understand how endoclips for routine prophylactic clip closure can be valued by payers, priced by industry, and reimbursed to gastroenterology practices and hospitals. We aimed to determine the optimal clinical strategy to implement routine prophylactic clip closure in practice from a payer perspective, considering important patient- and polyp-specific factors.

METHODS

A decision-analytic model was constructed to predict healthcare costs based on whether routine prophylactic clip closure was attempted to close a submucosal defect after complete endoscopic resection of a large (≥ 20 mm) colon polyp with one of several programmatic clinical strategies. The reference case was a 65-year-old Medicare-eligible individual with at least one medical comorbidity undergoing colonoscopy consistent with patient demographics in recent clinical trial data². The design of our model is described in **Supplement Figure 1** and complies

with the CHEERS checklist and methodologic recommendations by the Second Panel on Cost-Effectiveness in Health and Medicine.⁵ Model inputs are detailed in **Supplement Table 1**.

RESULTS

The baseline risk of post-procedure bleeding after endoscopic resection of a large colon polyp without prophylactic clip closure was 7.0% (95% confidence interval [CI]=4.9-9.7%) in pooled randomized clinical trial data of 899 patients. The risk was higher for right-sided colon polyps proximal to or including the hepatic flexure (9.5% [95% CI 6.6-13.2%]) and lower for left-sided colon polyps (1.4% [95% CI 0.0-4.9%]). The average cost of one bleeding event was \$6,458.05 considering our base case of a 65-year-old patient with at least one medical comorbidity. Translating this risk into cost burden spread across all patients undergoing resection of a large polyp resulted in \$453.44 excess cost-per-patient, and specifically \$614.11 for every patient with a large right-sided polyp, to cover the risk and potential costs associated with post-procedure bleeding. The cost burden increased with greater medical comorbidities necessitating higher payer reimbursement to manage post-procedure bleeding (data not shown).

Routine clip closure following endoscopic resection of large colon polyps was cost-saving overall, but this finding was driven solely by prophylactic clip closure of right-sided polyps. Clip closure after EMR of a large right-sided polyp resulted in a 70.7% risk reduction in post-polypectomy bleeding compared to no clip closure (**Figure 1**). Cost-savings with clip closure were \$434.09 for a large right-sided polyp. Routine clip closure after EMR of a large left-sided polyp did not decrease the post-procedure bleeding rate and were not cost-saving. When examining other patient and polyp factors, polyp location was the most important polyp-specific factor driving cost-savings. Alternative routine clip closure strategies focused on extra-

large polyps (≥ 40 mm in diameter) regardless of location, or focused on individuals on periprocedural antithrombotic medications regardless of polyp characteristics, resulted in 62.9% and 69.2% respective risk reductions in post-procedure bleeding; however, the absolute decrease in risk was small, and the cost savings were therefore less pronounced.

DISCUSSION

We performed a budget impact analysis, to determine the value of prophylactic clip closure to prevent post-procedure bleeding after endoscopic resection of large colon polyps using CMS billing codes in a Medicare-eligible population. The cost-burden of managing potential post-procedure bleeding increases procedural costs to payers by \$319.80 to \$769.98 for all patients undergoing endoscopic resection of a large colon polyp. Prophylactic clip closure as the standard-of-care after resection of large colon polyps, particularly of right-sided polyps ≥ 20 mm, was cost-saving to the payer.

Reimbursement is often the major barrier to broad adoption of promising advanced endoscopic techniques, especially when these techniques propose using established endoscopic technology which payers do not reimburse, such as clips.^{6,7} As GI experts continue to question the high rate of surgery for benign colon polyps, the lack of sustainable reimbursement models for complex luminal procedures certainly does not encourage adoption beyond tertiary care centers which are able to absorb costs in other areas.⁸ At the crux of this problem is the discrepancy between payers who achieve cost-savings and gastroenterology practices who pay for endoclips under a fixed reimbursement structure—ultimately at the expense of the patient.

There are several important limitations to consider. Our study used CMS cost data tied to common procedural codes which are generalizable across several payers; while commercial

payers use CMS codes, reimbursement varies substantially. A third recent RCT by Albéniz, *et al.* was not considered in the current study, because it only included individuals with an expected high bleeding risk.⁴ Finally, it is important to recognize that budget impact analysis is a systems-level analysis that does not compare cost to clinical appropriateness, which is individualized based on the clinical needs of the patient.

In summary, we performed a budget impact analysis to evaluate the expected cost-savings to payers and likelihood of cost-savings to gastroenterology practices by incorporating prophylactic clip closure to reduce the risk of post-procedure bleeding in managing large colon polyps using Medicare cost data and CMS billing codes to outline the general model. Clinical efficacy and cost-savings in clip closure after resection of a large colon polyps, particularly those located in the right colon, warrants creation of a defined reimbursement pathway for this complex luminal endoscopic technique and improve clinical adoption outside of tertiary care centers. Furthermore, our study provides an example of the utility of budget impact analysis in supporting innovative reimbursement mechanisms toward adapting established endoscopic technologies to new clinical applications, while providing gastroenterology practices with evidence to negotiate alternative reimbursement to support new clinical avenues which improve patient outcomes.

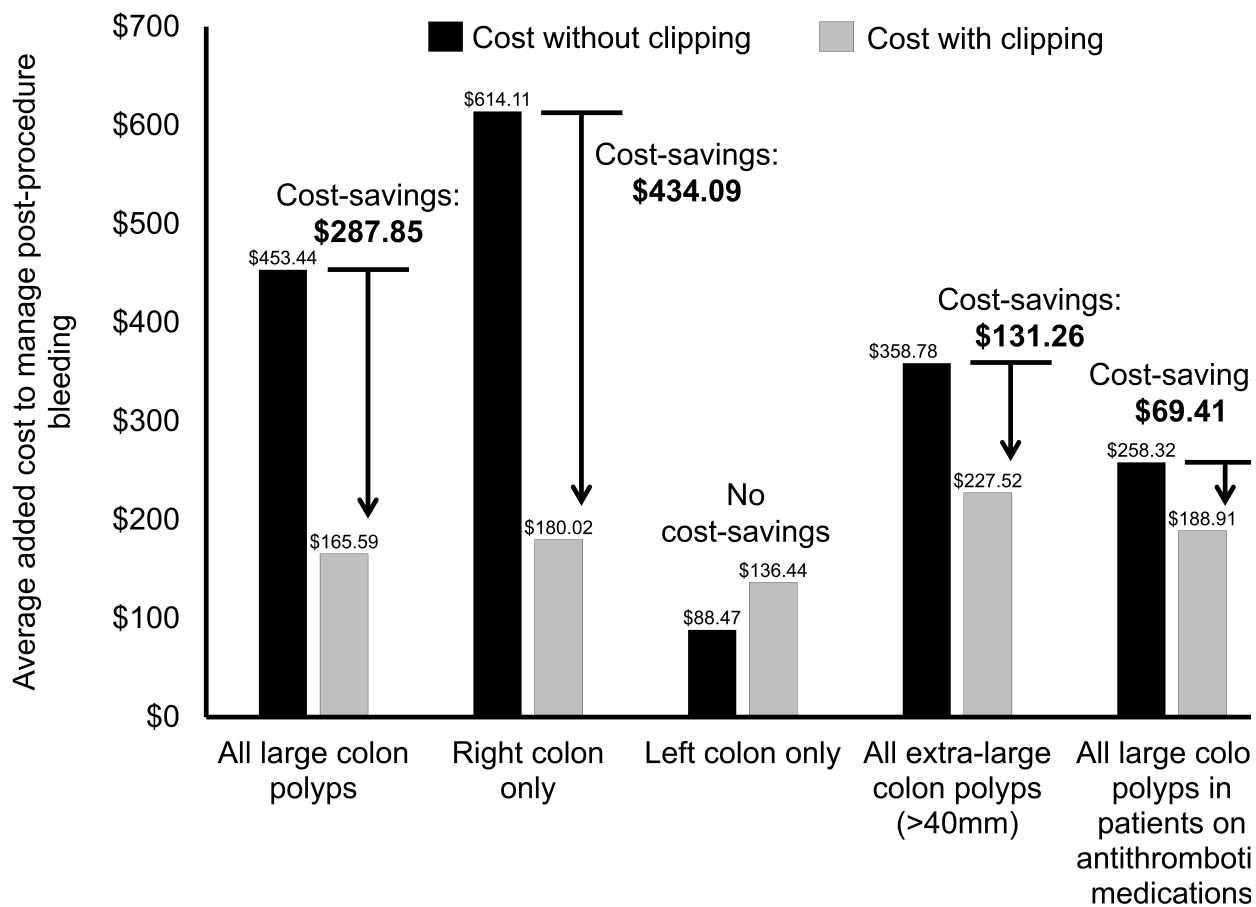
REFERENCES

1. Burgess, *et al.* Clin Gastroenterol Hepatol 2014;12:651-661.
2. Pohl H, *et al.* Gastroenterology 2019;157(4):977-984.
3. Feagins, *et al.* Gastroenterology 2019;157(4):967-976.
4. Albéniz E, *et al.* Gastroenterology 2019 July. Epub ahead of print.
5. Sanders GD, *et al.* JAMA 2016;316:1093-1103.
6. Shah ED, *et al.* Gastrointest Endosc 2019;89(2):264-273.
7. Muthusamy VR, *et al.* Clin Gastroenterol Hepatol 2019;17:580-583.
8. Rex D. Endoscopy 2018;50:657-659.

FIGURE LEGEND

Figure 1: Costs and cost-savings with routine prophylactic clip closure. Routine clip closure after resecting large non-pedunculated polyps in the right colon was the most cost-saving strategy

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Model inputs

Prophylactic clip closure in this setting is primarily intended to reduce the risk of post-procedure bleeding. We defined post-procedure bleeding as a clinically significant bleeding event that required hospitalization, blood transfusion, a repeat colonoscopy or any other invasive intervention, and that occurred up to 30 days following endoscopic resection of a large colon polyp. Our model assigned a specific risk of post-procedure bleeding based on the extent of clip closure. We assumed that the extent of clip closure depended on two factors: (1) whether prophylactic clip closure was attempted or not, and (2) whether attempted clip closure was technically successful in completely closing the post-resection site (or whether clip closure was attempted but incomplete). Based on these assumptions, we modeled three distinct states of clip closure: complete clip closure, incomplete clip closure, or no attempt at clip closure. Our model assumed that the extent of clip closure achieved would account for technical factors including the brand of endoclip and technical skill of endoscopist. We also assumed that a median number of four clips would be deployed in routine clip closure of large colon polyps^{7,13,14}.

We conducted a systematic review of the literature to identify post-procedure bleeding risks associated with prophylactic clip closure and rates of technical success in achieving complete clip closure. The systematic review was conducted according to methodologic guidelines in the PRISMA statement. Two authors (ES and SM) independently conducted a literature search of PubMed and EMBASE (inception to June 6, 2019), to identify randomized controlled trials evaluating clip closure *vs.* no clip closure after complete endoscopic resection of large colon polyps (≥ 20 mm). Discrepancies on study eligibility were resolved by consensus among authors. We also evaluated eligibility of trials identified in prior relevant systematic reviews¹⁵⁻¹⁷. Of 171 identified total abstracts in our literature search, 11 trials underwent full-text

review. Nine studies had no extractable data relevant to our model, due to lack of data on polyps $\geq 20\text{mm}$ ^{18–20}, inclusion of pedunculated polyps^{21–23}, lack of data on polyp location²⁴, randomization of selected high-risk individuals⁸ or retrospective study design¹⁴. The remaining two trials were used to develop model inputs using outcomes from 899 patients^{7,13}.

We extracted risks of post-procedure bleeding based on the extent of clip closure in eligible clinical trials in per-protocol analyses (i.e. individuals randomized to clip closure who received clip closure, and individuals randomized to no clip closure who did not receive clip closure). Per-protocol analysis was used to account for patient-specific factors which would make clip closure clinically necessary (or unnecessary) regardless of randomization which are relevant to exclude in decision analytic modeling. Specific risks of post-procedure bleeding were also extracted on several patient- and polyp-specific factors: location of polyp (right colon [hepatic flexure, cecum, and ascending colon] vs. left colon [transverse colon through rectum]), use of any anticoagulation or non-ASA antithrombotic therapy (held perioperatively and restarted at endoscopist discretion), and polyp diameter (20 to 39mm, compared to $\geq 40\text{mm}$). Corresponding authors of underlying trials were contacted to account for outcomes not reported in the original publication.

Our model was not designed to assess other potential adverse events associated with polypectomy more broadly, such as intraprocedural bleeding, post-procedure abdominal pain, perforation, or post-polypectomy syndrome, because the use of endoclips to close a post-resection site did not significantly change the frequency of these outcomes in prior studies.

Costs

Healthcare costs were extracted from the 2019 Center for Medicare & Medicaid Services Physician Fee Schedule (PFS) and Acute Inpatient Prospective Payment System (PPS)^{25,26}. We assumed that payers would not directly cover the cost of endoclips, which are borne directly by gastroenterology practices and hospitals in most cases. Rather, the use of endoclips would decrease overall healthcare costs to the payer by reducing the risk of post-procedure bleeding and associated costs of care. We assumed that usual care for post-procedure bleeding after endoscopic resection of a large colon polyp would involve an inpatient hospitalization with repeat colonoscopy for control of bleeding. Costs which did not depend on whether clip closure was performed, such as index colonoscopy and perioperative costs, were excluded from the model as these costs would not impact our findings.

Analysis

Budget impact analysis was conducted from a payer perspective to determine the average costs to manage post-procedure bleeding spread across all patients undergoing polypectomy, either (1) with prophylactic clip closure or (2) without prophylactic clip closure. We defined “cost-savings to the payer” associated with prophylactic clip closure by subtracting these average costs. The model employed a 30-day time horizon (with a 0% discount rate) consistent with the timeframe to define post-procedure bleeding.

Literature search criteria for systematic review

PubMed search string: (clip or endoclip* or hemoclip*) and (endoscop* or colonoscop* or "endoscopy"[MeSH]) and (bleed* or "hemorrhage"[MeSH]) and (polyp or "polyps"[MeSH])

EMBASE search string: ('gastrointestinal clip applicator'/exp OR 'gastrointestinal clip applicator' OR endoclip* OR hemoclip*) AND ('colonoscopy'/exp OR 'colonoscopy' OR 'gastrointestinal endoscopy'/exp OR 'gastrointestinal endoscopy') AND ('bleeding'/exp OR 'bleeding') AND ('colon polyp'/exp OR 'colon polyp')

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Supplement Table 1: Model inputs.

| Description | Base-case value | Range | Distribution | References |
|---|-----------------|-------|--------------|---|
| <i>Outcomes</i> | | | | |
| Technical success of complete clip closure | | | | Pohl, <i>et al.</i> (2018) ⁷ ; Feagins, <i>et al.</i> (2019) ¹³ |
| 1. All large colon polyps (≥ 20 mm) | 77.9% | | Beta; N: 429 | |
| 2. Right colon only | 76.7% | | Beta; N: 287 | |
| 3. Left colon only | 80.3% | | Beta; N: 142 | |
| 4. All extra-large colon polyps (≥ 40 mm) | 61.0% | | Beta; N: 82 | |
| 5. All large colon polyps in patients on antithrombotic medications | 73.5% | | Beta; N: 98 | |
| Rate of post-procedure bleeding (complete clip closure) | | | | Pohl, <i>et al.</i> (2018) ⁷ ; Feagins, <i>et al.</i> (2019) ¹³ |
| 1. All large colon polyps (≥ 20 mm) | 2.7% | | Beta; N: 334 | |
| 2. Right colon only | 2.7% | | Beta; N: 220 | |
| 3. Left colon only | 2.6% | | Beta; N: 114 | |
| 4. All extra-large colon polyps (≥ 40 mm) | 4.0% | | Beta; N: 50 | |
| 5. All large colon polyps in patients on antithrombotic medications | 2.8% | | Beta; N: 72 | |
| Rate of post-procedure bleeding (incomplete clip closure) | | | | Pohl, <i>et al.</i> (2018) ⁷ ; Feagins, <i>et al.</i> (2019) ¹³ |
| 1. All large colon polyps (≥ 20 mm) | 2.2% | | Beta; N: 95 | |
| 2. Right colon only | 3.1% | | Beta; N: 67 | |
| 3. Left colon only | 0.0% | | Beta; N: 28 | |
| 4. All extra-large colon polyps (≥ 40 mm) | 3.1% | | Beta; N: 44 | |
| 5. All large colon polyps in patients on antithrombotic medications | 3.8% | | Beta; N: 30 | |
| Rate of post-procedure bleeding (no attempt at clip closure) | | | | Pohl, <i>et al.</i> (2018) ⁷ ; Feagins, <i>et al.</i> (2019) ¹³ |
| 1. All large colon polyps (≥ 20 mm) | 7.0% | | Beta; N: 95 | |
| 2. Right colon only | 9.6% | | Beta; N: 67 | |
| 3. Left colon only | 1.4% | | Beta; N: 28 | |
| 4. All extra-large colon polyps (≥ 40 mm) | 5.6% | | Beta; N: 44 | |
| 5. All large colon polyps in patients on antithrombotic medications | 4.0% | | Beta; N: 30 | |
| <i>Costs</i> | | | | |
| Hospitalization for post-procedure bleeding with at least one comorbidity present (DRG 378) | \$6,458.05 | | | CMS Acute Inpatient Prospective Payment System databases ²⁶ |
| Initial hospital care (CPT 99223) | \$205.42 | | | Physician Fee Schedule ²⁵ |
| Day of discharge (CPT 99217) | \$108.84 | | | Physician Fee Schedule ²⁵ |
| Subsequent hospital care (CPT 99232) | \$73.88 | | | Physician Fee Schedule ²⁵ |
| Colonoscopy with control of bleeding (CPT 45382) | \$273.18 | | | Physician Fee Schedule ²⁵ |

CMS: Center for Medicare and Medicaid Services; CPT: Current Procedural Terminology; DRG: Diagnosis Related Group.

Supplement Figure 1: Model diagram.

