



Taeko Minegishi, MS, PhD, Geri Cramer, BRN, MBA, PhD
Boston Scientific Corporation, Marlborough, MA, USA

Boston Scientific
Advancing science for life™

BACKGROUND

In real-world data, identifying device usage can be challenging unless specific procedure codes are established. The ability to track both device usage and associated procedures is critical for evaluating real-world clinical outcomes and economic impacts of new technology. The OverStitch™ Endoscopic Suturing System can be used for procedures such as endoscopic sleeve gastropasty (ESG), transoral outlet reduction (TORe), and defect closure within the gastrointestinal tract, for which specific procedure coding is still in development.

We applied Latent Class Analysis (LCA), a probabilistic modelling technique to a real-world dataset utilizing the OverStitch device to attempt to subset patients into the primary procedures for which this device was used.

METHODS

Premier Healthcare Database was searched to identify outpatient encounters associated with the OverStitch device using keyword search, covering the period from Jan 1st, 2019, and October 31st, 2024.

The Center for Medicare & Medicaid Services (CMS) established new HCPCS code to report the ESG and TORe procedures (C9784 and C9785) performed in the outpatient setting starting July 1st, 2024.

A retrospective analysis of 3,266 outpatient encounters associated with the OverStitch device between Jan 1st, 2019, and June 30th, 2023, was conducted to build a LCA model. The model included patient demographics, claims, and diagnosis codes. The most parsimonious model was selected for reporting.

The outpatient encounters that occurred between July 1st, 2024, and October 31st, 2024, were used to conduct a qualitative validation of the model. Among the 948 encounters reported with the OverStitch device, only 41 were coded with C9784 or C9785.

RESULTS

A four-class model provided optimal fit and interpretability. Three of the subgroups aligned with our anticipated characteristics of patients undergoing ESG or TORe. Table 1 presents the profile of the predicted probability of selected variables for each group.

Group 1 (34%) and **Group 2** (24%) were likely indicative of ESG and TORe procedures, characterized by younger females (under 65 years), with a gastroenterologist or surgeon as the attending physician, and largely commercial insurance coverage. Patients in both groups were diagnosed with obesity, gastroesophageal reflux disease (GERD), and/or had a history of bariatric surgery. A key distinguishing feature of Group 1 was the presence of fewer than four co-existing ICD-10 codes, suggesting a healthier cohort. In contrast, Group 2 had more than three ICD-10 codes, likely indicating a sicker population with more prominent characteristics associated with a post-bariatric surgery revisional procedure (TORe). **Group 3** (27%) consisted of older Medicare beneficiaries with multiple ICD-10 codes, including GERD and obesity, also likely suggestive of TORe procedures. **Group 4**, the smallest subgroup (14%), was composed of younger patients treated by gastroenterologists. This group were characterized by patients with ICD-10 codes associated with the colon (Z12.11 and Z57.30) and included fewer ICD-10 codes typically associated with an obesity procedure.

VALIDATION

Among the 948 outpatient encounters associated with the OverStitch device since July 1st, 2024, only 41 encounters (4%) were coded with HCPCS codes C9784 or C9785. When the final model was applied to these cases, all 41 encounters were classified in Group 1, 2 or 3 (Table 2). Among the 12 encounters classified into Group 1, procedures were evenly split between ESG and TORe. In contrast, Groups 2 consisted predominantly TORe procedures (24 out of 26), while Group 3 included three TORe procedures. Validation was conducted qualitatively due to the newness and underreporting of HCPCS codes C9784 and C9785. Given the limited data, the findings suggest that the LCA is sensitive but not specific to ESG and TORe procedures. This study is still underdevelopment and has several limitations, including a low volume of encounters, underutilization of HCPCS codes, and limited specificity of the LCA model due to minimal characteristic difference between ESG and TORe.

CONCLUSIONS

We classified OverStitch encounters into those likely to be ESG and TORe using LCA. This approach has the potential to enhance the understanding of the clinical and economic outcomes of using the OverStitch device in endobariatric procedures. This approach may be beneficial to isolate devices and procedures within real-world data when procedure codes are not available.

REFERENCES

- C9784: Gastric restrictive procedure, endoscopic sleeve gastropasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components.
C9785: Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components.

TABLE 1 LCA Results

Predicted probability of patient demographics and claims

| | Variables | Group 1 | Group 2 | Group 3 | Group 4 |
|-----------------------|--------------------|---------|---------|---------|---------|
| Gender | Female | 64% | 86% | 48% | 50% |
| Age Group | < 45 | 31% | 30% | 3% | 4% |
| | 45-55 | 23% | 34% | 10% | 32% |
| | 55-65 | 21% | 25% | 23% | 30% |
| | 65-75 | 17% | 9% | 39% | 25% |
| | age75< | 8% | 1% | 24% | 10% |
| Attending Physician | Surgery | 23% | 42% | 9% | 0% |
| | Internal Medicine | 15% | 11% | 32% | 13% |
| | Gastroenterologist | 59% | 45% | 58% | 87% |
| | Other | 3% | 2% | 2% | 0% |
| Payer | Medicare | 28% | 23% | 65% | 33% |
| | Medicaid | 11% | 17% | 3% | 10% |
| | Commercial | 46% | 46% | 28% | 56% |
| | Self-Pay | 10% | 11% | 1% | 1% |
| | Other | 4% | 3% | 3% | 0% |
| Number of ICD10 codes | 1-3 | 100% | 0% | 0% | 55% |
| | 4-8 | 0% | 89% | 84% | 44% |
| | 8< | 0% | 11% | 16% | 1% |

Predicted probability of ICD-10 Codes

| Code | Description | Group 1 | Group 2 | Group 3 | Group 4 |
|---------|---|---------|---------|---------|---------|
| E11.9 | Type 2 diabetes mellitus without complications | 2% | 16% | 21% | 12% |
| E66.01 | Morbid (severe) obesity due to excess calories | 12% | 43% | 4% | 3% |
| E66.9 | Obesity, unspecified | 12% | 25% | 16% | 9% |
| E78.00 | Pure hypercholesterolemia, unspecified | 1% | 6% | 17% | 22% |
| E78.5 | Hyperlipidemia, unspecified | 6% | 16% | 39% | 15% |
| F41.9 | Anxiety disorder, unspecified | 4% | 28% | 13% | 4% |
| I10 | Essential (primary) hypertension | 17% | 47% | 64% | 39% |
| I25.10 | Atherosclerotic heart disease of native coronary artery without angina pectoris | 1% | 1% | 22% | 5% |
| J45.909 | Unspecified asthma, uncomplicated | 3% | 22% | 9% | 4% |
| K21.9 | Gastro-esophageal reflux disease without esophagitis | 22% | 54% | 56% | 9% |
| K22.0 | Achalasia of cardia | 9% | 3% | 24% | 0% |
| K57.30 | Diverticulosis of large intestine without perforation or abscess without bleeding | 1% | 1% | 4% | 36% |
| Z12.11 | Encounter for screening for malignant neoplasm of colon | 0% | 0% | 0% | 70% |
| Z79.82 | Long term (current) use of aspirin | 2% | 6% | 23% | 1% |
| Z79.899 | Other long term (current) drug therapy | 15% | 52% | 43% | 4% |
| Z80.0 | Family history of malignant neoplasm of digestive organs | 2% | 3% | 5% | 20% |
| Z86.010 | Personal history of colon polyps | 1% | 3% | 5% | 28% |
| Z87.891 | Personal history of nicotine dependence | 12% | 22% | 42% | 15% |
| Z98.84 | Bariatric surgery status | 20% | 57% | 7% | 2% |

TABLE 2 Model Validation

Number of encounters coded with HCPCS codes in each subgroup

| HCPCS Code | Group 1 | Group 2 | Group 3 | Group 4 |
|--------------|---------|---------|---------|---------|
| ESG / C9784 | 6 | 2 | 0 | 0 |
| TORe / C9785 | 6 | 24 | 3 | 0 |