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Safety and Performance of MIRUS™ Circular Stapler Used for The Creation of End-to-End, End-to-Side and Side-to- Side Anastomosis in Both Open and Endoscopic Surgeries Throughout the Alimentary Tract

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ABSTRACT

Background: The MIRUS™ Circular Stapler is used for alimentary tract anastomosis in open and endoscopic surgeries; however, evidence on its long-term post-market safety and clinical performance remains limited. This study aimed to evaluate the safety and performance of the MIRUS™ Circular Stapler in routine clinical practice.
Methods: This was an open-label, retrospective, multicenter, observational, study conducted at two tertiary care centers in India. Data of patients who underwent alimentary tract anastomosis using the MIRUS™ Circular Stapler and completed at least 6 months of postoperative follow-up were included. The primary outcome was the incidence of wound infection within 6 months. Secondary outcomes included intraoperative bleeding, surgical site infection (SSI), stapler misapplication, device malfunction, anastomotic leakage, length of hospital stay, reoperation, and device-related adverse events (AEs). Descriptive statistics were used to summarize study findings.
Results: A total of 207 patients (mean age, 51.64 ± 13.99 years; 66.18% male) using the MIRUS™ Circular Stapler were included. The mean operative duration was 178.48 ± 39.62 minutes. No cases of intraoperative bleeding, stapler misapplication, stricture, fistula formation, or device malfunction were reported. SSI occurred in 9 patients (4.35%), while anastomotic leakage was observed in 11 patients (5.31%). At hospital discharge, 36 patients (17.39%) experienced AEs or serious AEs, with SSI being the most common event (11.59%). No procedure-related complications, device-related complications, or additional AEs were reported during the 30-day, 6-month, or 12-month follow-up.
Conclusion: The MIRUS™ Circular Stapler demonstrated a favourable safety profile, highlighting its safe and effective use for gastrointestinal anastomosis in both open and endoscopic surgeries.

Keywords: *Circular stapler, gastrointestinal anastomosis, surgical stapler, safety, real-world evidence.*

INTRODUCTION

Gastrointestinal anastomosis is a fundamental component of alimentary tract surgery, performed to restore bowel continuity following resection for benign or malignant diseases [1 2]. Traditionally, anastomoses were constructed using hand-sewn techniques; however, the introduction of mechanical stapling devices has significantly improved surgical efficiency, standardization, and reproducibility [3]. Stapled anastomoses are associated with reduced operative time, consistent tissue

approximation, and favourable postoperative outcomes when compared with conventional suturing techniques [4]. Circular staplers have become widely adopted for creating end-to-end, end-to-side, and side-to-side anastomoses throughout the gastrointestinal tract, especially in colorectal, esophageal, and gastric surgeries [5 6].

Anastomotic integrity remains one of the most critical determinants of postoperative success, as complications such as anastomotic leakage, bleeding, stricture formation, and infection contribute substantially to morbidity, mortality, prolonged hospitalization, and healthcare costs [7 8]. Consequently, continuous innovations in stapling technology have focused on improving staple formation, tissue compression, and ease of use to enhance surgical safety and clinical outcomes [9 10]. Recent evidence suggests that advances in circular stapler design may influence the incidence of anastomotic complications and improve procedural reliability [11].

The MIRUS™ Circular Stapler (Meril Endo Surgery Pvt. Ltd., Vapi, India) is a disposable mechanical stapling device designed for use throughout the alimentary tract in both open and endoscopic procedures. It simultaneously creates a circular anastomosis by deploying concentric rows of titanium staples while excising excess tissue with an integrated circular knife. The device is indicated for the creation of end-to-end, end-to-side, and side-to-side anastomoses and is available in multiple diameters to accommodate varying anatomical requirements [12]. The United States Food and Drug Administration (FDA) has determined the MIRUS™ Circular Stapler to be substantially equivalent to circular stapling devices and approved for use throughout the alimentary tract for end to end, end to side and side to side anastomoses [13].

Despite widespread use of circular staplers in gastrointestinal surgery, clinical data evaluating the safety and performance of newer devices such as the MIRUS™ Circular Stapler across diverse gastrointestinal procedures remain limited. Therefore, the present study was undertaken to evaluate the safety and performance of the MIRUS™ Circular Stapler in the creation of end-to-end, end-to-side, and side-to-side anastomoses during open and endoscopic surgeries throughout the alimentary tract. The findings are expected to provide valuable evidence regarding its clinical effectiveness, procedural reliability, and associated postoperative outcomes in routine surgical practice.

METHODOLOGY

Study Design and Setting

This was an open-label, retrospective, multicenter, observational, study conducted across various centers in India to evaluate the safety and performance of the MIRUS™ Circular Stapler in both open and endoscopic surgeries involving the alimentary tract. As the study involved retrospective analysis of existing medical records without any intervention or alteration to standard patient care, a waiver of written informed consent was obtained from the Institutional Ethics

Study Population

The study included all consecutive patients who underwent creation of end-to-end, end-to-side, or side-to-side anastomosis of the alimentary tract using the MIRUS™ Circular Stapler during open or endoscopic surgical procedures and who had completed a minimum postoperative follow-up of 6 months. Patients were eligible for inclusion if they had been treated with the MIRUS™ Circular Stapler and had adequate follow-up data available for assessment. Patients who were not treated using the MIRUS™ Circular Stapler or those who could not be contacted or lacked available follow-up information at 6 months after surgery were excluded from the study.

Device specification

Figure 1: A representative image of the MIRUS™ Circular Stapler (Meril Endo Surgery Pvt. Ltd.)

The MIRUS™ Circular Stapler (Meril Endo Surgery Pvt. Ltd).is a single-use surgical stapling device designed for creating end-to-end, end-to-side, and side-to-side anastomoses throughout the alimentary tract during both open and endoscopic procedures. The device is available in two-row and three-row staple line configurations, with the three-row design intended to enhance anastomotic security and hemostasis. It features a stainless-steel anvil shaft with an extended purse-string tying area and an adjustable staple height mechanism with a staple compression gauge to facilitate optimal tissue compression. The stapler produces B-shaped titanium staples for secure tissue approximation and incorporates an integrated circular knife for simultaneous tissue transection. It is available in multiple diameters, including 21, 24, 25, 26, 29, 31, and 32 mm, allowing selection of the appropriate size according to the surgical indication and tissue characteristics (**Figure 1 & 2)** [14].

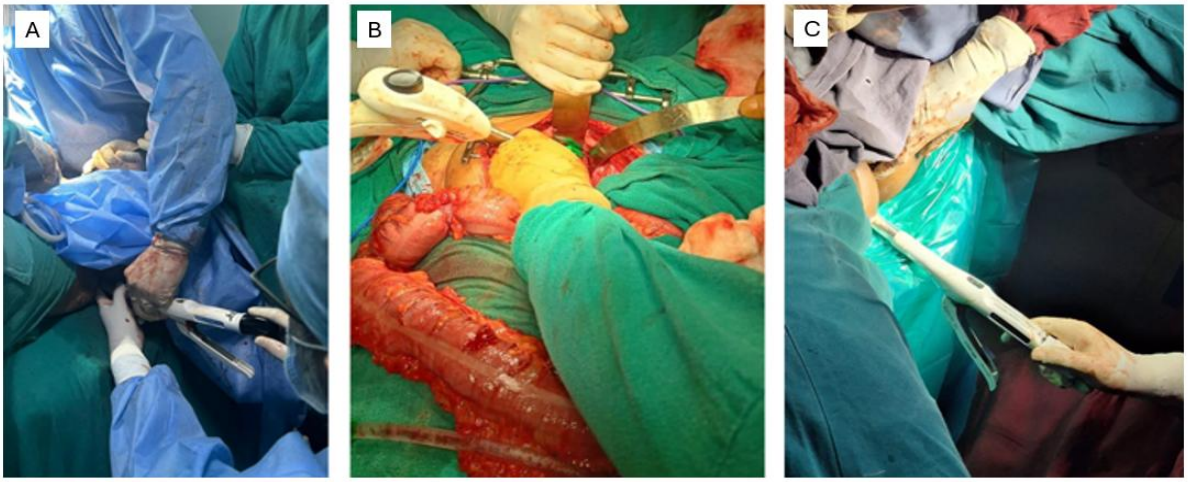

Figure 2. Representative intraoperative images demonstrating the use of the MIRUS™ Circular Stapler during gastrointestinal surgery. (A) Surgical preparation and positioning of the circular stapler during gastrointestinal surgery. (B) Intraoperative deployment of the stapler for creation of the anastomosis following bowel resection. (C) Completion of the anastomotic procedure using the MIRUS™ Circular Stapler.

Data Collection

Baseline demographic characteristics, clinical characteristics, procedural details, device-related information, and follow-up outcomes were extracted from medical records and documented using a standardized Case Report Form (CRF).

Study outcomes

The primary outcome was the incidence of wound infection occurring within 6 months following surgery. Secondary endpoints included the incidence of intraoperative bleeding; mean operative time; incidence of SSI within 6 months; incidence of stapler misapplication, defined as the application of staples to incorrect tissue or use of an inappropriate stapler size; incidence of device malfunction or device failure occurring intraoperatively or postoperatively, including but not limited to failure to fire, stapler misfiring, difficulty in firing, tissue tearing, tissue injury, slippage, failure to cut, difficulty in device removal, sticking, and failure to retract when used according to the instructions for use; length of hospital stay (days); incidence of anastomotic leakage within 6 months postoperatively; incidence of reoperation or additional surgical procedures; incidence of adverse events (AEs) related to the use of the MIRUS™ Circular Stapler, including bleeding, sepsis, infection, leakage, wound dehiscence, abscess formation, fistula formation, hemorrhage, and other related complications; and the incidence of additional surgical procedures required as a consequence of device malfunction, device failure, or device-related AEs.

Sample Size Calculation

The sample size was determined based on a reference wound infection rate of 28.5% reported in previous studies [15]. Assuming a similar event rate, with a two-sided significance level of 5%, power of 80%, and a confidence interval half-width of 0.0625 using the Wilson method for confidence interval estimation, a minimum sample size of 207 patients was required. To ensure adequate evaluable data, approximately 210 patients were targeted for inclusion in the study.

Statistical Analysis

Microsoft Excel and SPSS (version 27) were used for data entry, cleaning, and analysis. Continuous variables are presented as mean ± standard deviation (SD), and categorical variables are summarised as frequencies and percentages.

RESULTS:

Baseline Demographic and Clinical Characteristics

Total of 207 patients were enrolled with most being male (66.18%) with the mean age of 51.64 ± 13.99 years. The mean height, weight, and body mass index (BMI) of the patients were 165.10 ± 9.47 cm, 69.56 ± 10.52 kg, and 25.72 ± 4.56

kg/m², respectively. Baseline vital signs were within normal physiological ranges, with a mean heart rate of 76.70 ± 5.89 bpm, systolic blood pressure of 121.65 ± 6.87 mmHg, and diastolic blood pressure of 78.77 ± 6.02 mmHg (**Table 1).**

Regarding patient medical history, hypertension was the most common medical condition (26.57%), followed by type 2 diabetes mellitus (17.39%) and hypothyroidism (11.59%). Malignancies constituted the primary underlying disease indications for surgery, with rectal cancer being the most prevalent diagnosis (58.94%), followed by rectosigmoid colon cancer (16.91%) and colon cancer (14.98%). Additional medical conditions such as rheumatoid arthritis, atrial fibrillation, chronic obstructive pulmonary disease, acute tuberculosis, and permanent pacemaker implantation were reported in a small proportion of patients. Furthermore, 20.29% of the study population had a history of smoking (**Table 1).**

Table 1. Baseline Demographic and clinical characteristics of the study population (N = 207)

Demography	
Gender, **n (%)**	
Male	137 (66.18)
Female	70 (33.82)
Race	**Asian**
Age (years), Mean ± SD	**51.64 ± 13.99**
Age Bifurcation, **n (%)**	
22 – 42	51 (24.64)
43 – 63	112 (54.11)
64 – 84	44 (21.26)
Height (cm), Mean ± SD	165.10 ± 9.47
Weight (kg), Mean ± SD	69.56 ± 10.52
BMI (kg/m^2), Mean ± SD	25.72 ± 4.56
Vital signs, Mean ± SD	
Heart Rate (bpm)	76.70 ± 5.89
Systolic BP (mmHg)	121.65 ± 6.87
Diastolic BP (mmHg)	78.77 ± 6.02
Medical History, n (%)	
Hypertension	55 (26.57)
Type 2 Diabetes Mellitus	36 (17.39)
Hypothyroidism	24 (11.59)
Cancer/ Tumour, n (%)	
CA COLON	31 (14.98)
CA Colorectal	3 (1.45)
CA ESOPHAGUS	1 (0.48)
CA G.E JUNCTION JEJUNOSTOMY	1 (0.48)
CA OVARIAN	8 (3.86)
CA RECTOSIGMOD COLON	35 (16.91)
CA RECTUM	122 (58.94)
CA SIGMOID COLON	1 (0.48)
CA STOMACH	5 (2.42)
Any Other	**7 (3.38%)**
Acute TB	1 (0.48)
Atrial fibrillation	1 (0.48)
Chronic Obstructive pulmonary diseases	1 (0.48)
Permanent Pacemaker	1 (0.48)
Rheumatoid arthritis	3 (1.45)
Smokers	**42 (20.29)**

Procedural Indications and Intraoperative Findings

The most common procedural indication was rectal cancer, observed in 62 patients (29.95%), followed by advanced rectal cancer in 53 patients (25.60%). Gastric cancer and colon cancer were reported in 17 (8.21%) and 15 (7.25%) patients, respectively, while intestinal obstruction and colon bleeding were observed in 13 (6.28%) and 12 (5.80%) patients. Less frequent indications included esophageal cancer (4.83%), large irregular colon mass (2.90%), massive ascites (2.42%), familial adenomatous polyposis (1.45%), hemorrhagic ascites (1.45%), and ulcerative colitis with rectosigmoid growth (1.45%). Rare procedural findings included rectosigmoid cancer (0.97%), colorectal cancer (0.48%), gastroesophageal junction mass (0.48%), and rectal bleeding (0.48%) (**Table 2).**

Table 2. Procedural Indications and Intraoperative Findings Among Patients Undergoing Anastomosis Using the MIRUS™ Circular Stapler (N = 207)

Procedural Findings	n (%)
Advanced Rectal Cancer	53 (25.60)
Colon Bleeding	12 (5.80)
Colon Cancer	15 (7.25)
Colorectal Cancer	1 (0.48)
Esophageal Cancer	10 (4.83)
Familial Adenomatous Polyposis	3 (1.45)
Gastric Cancer	17 (8.21)
GE Junction Mass	1 (0.48)
Hemorrhagic Ascites	3 (1.45)
Intestinal Obstruction	13 (6.28)
Large Irregular Mass COLON	6 (2.90)
Massive Ascites	5 (2.42)
Rectal Bleeding	1 (0.48)
Rectal Cancer	62 (29.95)
Rectosigmoid Cancer	2 (0.97)
Ulcerative Colitis with Rectosigmoid Growth	3 (1.45)

Surgical and Procedural Characteristics

Among the 207 procedures performed using the MIRUS™ Circular Stapler, the rectum was the most common surgical site (62.80%), followed by the colon (19.81%) and abdominal procedures (8.70%). Surgeries involving the esophagus, ovary, and colorectum were less frequent, representing 4.35%, 3.86%, and 0.48% of cases, respectively.

Regarding the type of surgery performed, low anterior resection was the most common procedure (46.38%), followed by Hartmann's reversal (25.60%) and colectomy (15.94%). Esophagectomy, ovariectomy, and gastrectomy were performed in 4.83%, 3.86%, and 3.38% patients, respectively. Most procedures were intended for resection followed by creation of anastomosis, which was reported in 133 patients (64.25%). Resection alone was performed in 67 patients (32.37%), while transection, resection, and creation of anastomosis were carried out in 6 patients (2.90%). Creation of anastomosis alone was reported in 1 patient (0.48%) (**Table 3**).

With respect to the surgical category, gastrointestinal anastomosis combined with colorectal surgery was the most common, accounting for 101 procedures (48.79%), followed closely by colorectal surgery alone in 91 patients (43.96%). Gastrointestinal anastomosis combined with gastric surgery was performed in 7 patients (3.38%), while esophageal surgery was reported in 1 patient (0.48%). The mean duration of surgery was 178.48 ± 39.62 minutes. A total of 207 MIRUS™ Circular Staplers were utilized, corresponding to one device per procedure (**Table 3**).

Table 3. Surgical and Procedural Characteristics of Patients Treated with the MIRUS™ Circular Stapler (N = 207)

Procedural Details	n (%)
Location of Surgery	
Abdominal	18 (8.70)
Colon	41 (19.81)
Colorectum	1 (0.48)
oesophagus	9 (4.35)
Ovary	8 (3.86)
Rectum	130 (62.80)
Type of Surgery	
Colectomy	33 (15.94)
Esophagectomy	10 (4.83)
Gastrectomy	7 (3.38)
Hartmann's Reversal	53 (25.60)
Low Anterior Resection	96 (46.38)
Ovariectomy	8 (3.86)
Type of Surgery (Intended for)	
Transection+ Resection+ Creation of anastomoses	6 (2.90)
Resection+ Creation of anastomoses	133(64.25)
Resection	67 (32.37)
Creation of anastomoses	1 (0.48)
Name of Surgery	
Gastrointestinal Anastomoses+ Colorectal Surgery	101 (48.79)

Colorectal Surgery	91 (43.96)
Esophageal Surgery	1 (0.48)
Gastrointestinal Anastomoses+ Gastric Surgery	7 (3.38)
Duration of procedure (min), Mean ± SD	**178.48 ± 39.62**
Total Device	**207**

Safety and Performance Outcomes

The safety assessment demonstrated a favourable safety profile for the MIRUS™ Circular Stapler. No cases of intraoperative bleeding, stricture formation, fistula formation, stapler misapplication, or device malfunction were reported. SSI occurred in 9 patients (4.35%). During the postoperative follow-up period, no procedure-related complications, device-related complications, misapplied staplers, or device malfunctions were observed. Anastomotic leakage was reported in 11 patients (5.31%) (**Table 4**).

Table 4. Safety and Performance Outcomes Following Use of the MIRUS™ Circular Stapler (N = 207)

Parameter	**n (%)**
Safety Outcomes	
Bleeding	0 (0.0)
Stricture	0 (0.0)
Fistula Formation	0 (0.0)
Misapplied Stapler	0 (0.0)
Device Malfunction	0 (0.0)
Surgical Site Infection	9 (4.35)
Post-Procedural Outcomes	
Procedure-related Complications	0 (0.0)
Device-related Complications	0 (0.0)
Misapplied Stapler	0 (0.0)
Anastomotic Leakage	11 (5.31)
Device Malfunction	0 (0.0)

A total of 36 patients (17.39%) experienced AEs or serious AEs at the time of hospital discharge. SSI was the most frequently reported event (11.59%). Other reported events included device malfunction (1.45%), inadequate blood supply to the surgical site (1.45%), hypertension-related complications (1.45%), and nutritional depletion (1.45%) (**Table 5)**. No major complications, surgical site infections, AEs, or serious AeS were reported during the 30-day, 6-month, and 12-month follow-up periods.

Table 5. Safety Profile of the MIRUS™ Circular Stapler at Hospital Discharge (N = 207)

Safety outcome	**n (%)**
Patients with any AE/SAE at discharge	36 (17.39)
Description of Event	
Surgical site infection	24 (11.59)
Device malfunction	3 (1.45)
Inadequate blood supply to the surgical site	3 (1.45)
Hypertension-related complication	3 (1.45)
Nutritional depletion	3 (1.45)

Abbreviations: AE, adverse event; SAE, serious adverse event.

DISCUSSION:

The introduction of circular staplers has significantly advanced colorectal surgery by reducing operative time, minimizing dependence on surgeon expertise, standardizing anastomotic techniques, and improving overall clinical outcomes [16]. To the best of our knowledge, this is the first real-world evidence evaluating the safety and performance of the MIRUS™ Circular Stapler in routine clinical practice.

Present study demonstrated an excellent safety profile, with no reported cases of intraoperative bleeding, stapler misapplication, stricture, fistula formation, or device malfunction, and low incidences of SSI and anastomotic leakage. These findings support the safe and effective use of the MIRUS™ circular stapler for gastrointestinal anastomosis in both open and endoscopic surgical procedures.

The present study population primarily comprised of patients undergoing surgery for rectal and colorectal malignancies, reflecting current surgical practice where stapled colorectal anastomosis is frequently employed. Low anterior resection represented the most common surgical procedure, consistent with the predominance of rectal cancer in the study cohort. The mean operative duration was 2.97 ± 0.66 hours (178.48 ± 39.62 minutes), demonstrating efficient procedural

performance in routine clinical practice. Similarly, Herzig et al., 2020 reported colorectal carcinoma (44.6%) and diverticulitis (31.5%) as the most common surgical indications. However, the mean operative duration in their study was 4.1 ± 1.6 hours, which was longer than that observed in our cohort [17].

One of the principal findings was the absence of device-related technical failures. No stapler malfunction, failure to fire, tissue injury attributable to the device, or stapler misapplication was observed throughout the study period. These findings suggest reliable staple formation and consistent device performance across different gastrointestinal procedures. The three-row staple line configuration and adjustable staple height incorporated in the MIRUS™ Circular Stapler may have contributed to secure tissue approximation and adequate hemostasis.

The incidence of surgical site infection (SSI, 4.35%) and anastomotic leakage (5.31%) observed in this study compares favourably with rates reported in published colorectal surgery literature. These findings are consistent with previous studies evaluating modern circular stapling devices. Sylla et al., 2022 demonstrated that the powered circular stapler was associated with significantly lower rates of anastomotic leakage (1.8% vs. 6.9%), infection (1.8% vs. 5.7%), and bleeding (1.8% vs. 9.2%) compared with a historical cohort, indicating improved clinical outcomes with newer stapling technology [18]. Likewise, Herzig et al., 2020 reported successful completion of anastomosis in all patients without device-related conversions or major technical failures, highlighting the dependable intraoperative performance of the powered circular stapler [17].

More recently, Ohtani et al., in a meta-analysis of 3,301 patients, demonstrated that the powered circular stapler significantly reduced anastomotic leakage compared with manual circular staplers, although no significant difference was observed in anastomotic bleeding. Consistent with these findings, the absence of device-related complications and technical failures in our study, together with the low incidence of postoperative complications, suggests that the MIRUS™ Circular Stapler provides reliable staple formation, secure tissue approximation, and favorable clinical outcomes in routine gastrointestinal surgery [19].

In this study although 17.39% of patients experienced AEs at hospital discharge, the majority were attributable to expected postoperative clinical conditions rather than device malfunction. Furthermore, no new serious AEs or device-related complications occurred during 30-day, 6-month, and 12-month follow-up, providing additional reassurance regarding the long-term safety profile of the device.

Overall, the findings support the effectiveness of the MIRUS™ Circular Stapler in achieving safe gastrointestinal anastomosis with a low incidence of clinically significant complications. These real-world data complement existing evidence regarding circular stapling devices and provide valuable post-market evidence supporting its routine clinical use [16 20]. However, the study has a few limitations. The retrospective observational design and the absence of a comparator group limit causal inference and preclude direct comparison with other circular stapling devices or manual anastomosis. Furthermore, the study was conducted at only two centers and relied on retrospective medical records, which may limit the generalizability of the findings and result in underreporting of minor AEs. Additionally, potential confounding factors were not adjusted for, and functional outcomes, patient-reported quality of life, cost-effectiveness, and long-term outcomes beyond 12 months were not evaluated.

CONCLUSION

Present study demonstrated that the MIRUS™ Circular Stapler exhibited a favorable safety and performance profile for gastrointestinal anastomosis in routine clinical practice. The device was associated with low rates of SSI and anastomotic leakage, with no reported intraoperative bleeding, stapler misapplication, stricture formation, fistula formation, or device malfunction. These real-world findings support the safe and effective use of the MIRUS™ Circular Stapler in both open and endoscopic gastrointestinal surgeries. However, prospective comparative studies with larger sample sizes and longer follow-up are warranted to further validate these findings and establish comparative effectiveness against other commercially available circular stapling devices.

Conflicts of interest

KKS is an employee of Meril Life Sciences Pvt. Ltd., Vapi, India, the manufacturer of the medical device evaluated in this study. His involvement was restricted to providing technical input regarding the device, assistance with study methodology, and editorial support during manuscript preparation. He did not participate in clinical decision-making, data collection, or analysis. All other authors declare no conflicts of interest.

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