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A Comparative Study of The Clinical Outcomes Using Conventional Manual Staplers and Circular Powered Staplers in Patients Undergoing Left Sided Colorectal Anastomosis

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Abstract

Aim: The aim of our study was to assess safety and efficacy of powered circular staplers for colorectal anastomosis and its comparison with conventional (manual staplers).

Method: It's a single institute, single surgeon based retrospective study to compare powered staplers with manual for the patient's undergoing anastomosis in colorectal surgery. We assessed the two techniques on the basis of type of surgery, technical problems, intraoperative leak, post-operative leak, blood transfusion, post-operative complication rates, adverse events, additional use of analgesics, antibiotics and readmission rates. SPSS version 20 was used to perform the statistical analysis.

Result: Study consisted of forty- eight patients who underwent surgery for colorectal disease. Mean operating time was same for both the groups (3.33 hours). One post-operative leak was observed in manual stapler anastomosis. Four patients had complications including anastomotic leak, anastomotic stricture, wound infection and perianal pain in our study, amongst them three patients underwent manual anastomosis while one patient underwent powered anastomosis. One patient in each arm required readmission. Three patients who underwent powered stapler anastomosis required higher analgesics and higher antibiotics as compared to none in manual, however it was not statistically significant. The mean pain score for patient in powered stapler and manual stapler was 2.96 and 2.92 respectively($p<0.851$), while mean length of stay was 7.04 for powered and 6.1 for manual stapler($p<0.08$).

Conclusion: In our preliminary study, powered stapler was safe and efficacious without any added complications and adverse events. We observed comparable intraoperative and higher trends of post-operative complication rates in manual stapler group.

Keywords: powered stapler; manual stapler; colorectal anastomosis; colorectal malignancy

Introduction

Globally, colorectal cancer (CRC) is the third leading cancer with an incidence of 1.9 million cases per year. It is a second leading cause of cancer related mortality worldwide attributing to 935,000 deaths annually. Of all the cancers, CRC contributes to 10% of the burden while its mortality is as high as 9.4%. The prevalence of Colorectal cancer is relatively low in India with the age standardized rate (ASR) of 7.2 per 100,000 population in males and 5.1 per 100,000 population in women [1]. Surgical management has been the standard of care for colorectal cancers [2]. Multimodality therapy including surgery, radiotherapy and chemotherapy in neoadjuvant or adjuvant settings is the standard treatment in advanced colorectal cancers [3]. Colorectal

anastomosis is an integral part of surgical treatment of CRC. Hültl and Fischer created the first stapler in 1908, which weighed more than 3.5 kg. It couldn't be set at the precise angle due to its size, and required a lot of strength for manipulation [4]. Aladar Petz applied 2 rows of 1 mm of nickel – silver alloy staples. This instrument weighed around 1.5 kg.[5] The first Soviet circular stapling device was presented in Donetsk, Ukraine, in 1957 [6]. More recently powered staplers have been designed with the same aim; addressing adverse device-to-tissue interaction where the staples and the knife blade are driven by a battery-operated electrical motor rather than manual force [7] Manual staplers are associated with low satisfaction particularly amongst smaller hand size surgeons [8].Robotic staplers that can be integrated with the robotic surgical system and manipulated by the console surgeon is the latest technological step [9] .Circular stapling devices have been used widespread as a standard practice in colorectal anastomosis (CRA) [10] . Powered circular stapler is a single-use anastomotic device that places a circular, double staggered row of titanium staples between intervening tissues. In a pre-clinical model powered stapler has confirmed an advantage of reduced force to fire, less movement during device application, and less leaking at the staple line compared to manual circular stapling [8,11,12]. The primary objective of our study was to compare powered circular staplers and manual staplers in assessing safety, efficacy and complication rates in real world setting.

Methodology

It is a retrospective observational study of a prospectively maintained data base in a tertiary care centre of those patients undergoing colorectal surgeries. The data was collected of those patients operated between June 2019 to November 2021.We included all those patients above the age of 18, patients requiring colorectal surgery with or without malignancy with the use of staplers for anastomosis. Patients with missing data about the variables considered and those who were planned for acute management or pregnancy were excluded. As per surgeons' clinical acumen and patients' choice, they were randomly assigned to receive powered or conventional stapler. Powered stapler (ECP) models included were 29mm (CDH-29P) and 31mm (CDH-31P) versions. Manual staplers included were 29mm (CDH- 29M) and 33 mm (CDH-33M). Steps in colorectal anastomosis included (1) selection of appropriate size gun; (2) securing the anvil in the distal end of the mobilized colonic conduit; (3) securely docking the anvil onto the end of the stapler gun, which is advanced from below; and (4) firing the stapler to complete the anastomosis. Procedures were carried out with minimum invasive approach that is laparoscopic/ Robotic or Open based on surgeons' preference. Laparoscopic to open conversion, the use of a hand port, proximal faecal diversion (loop ileostomy), and robotic assistance were all acceptable for inclusion in the study. Leak tests with air insufflation into the rectum and methylene blue leak test were completed to evaluate anastomotic integrity in every procedure. The surgeon had sole discretion over whether to perform a diverting ileostomy. Subjects were followed for signs of Anastomotic Leak (AL) or other complications as per institutional cancer follow up protocol.

Factors considered for assessment

Patients were preoperatively assessed for demographic data including age, gender, co–morbidities, BMI and performance scale. Patients were assessed intraoperatively for duration of surgery, intraoperative blood loss, and intraoperative leak using air leak test and methylene blue and donut quality post stapling. Post operatively they were assessed for any complications including anastomotic leak, requirement for blood transfusion, post operative pain scale, requirement for higher antibiotics, analgesics and the length of hospital stay (LOS). On discharge patients were followed up to 30 days after surgery and for any readmissions. Statistical analysis was conducted using SPSS version 20.0 (SPSS Inc, Chicago, Illinois, USA). Statistical analysis baseline characteristics were presented as mean for continuous variable and as percentage for categorical variables. Comparison between continuous variables were analyzed by student t test and categorical variable by chi square test.

Result

Study consisted of forty- eight patients who underwent surgery for colorectal disease. Our study had a male to female ratio of 2:1. (32:16) with a mean age of 58.69 years. A majority (97.9%) had comorbidities such as Diabetes mellitus (DM) or Hypertension (HTN) or others (47/48). All the

patients underwent surgery as management for colorectal disease. Thirty-one patients (64.67%) underwent laparoscopic anterior resection (LAR) followed by 9 patients who underwent open anterior resection (OAR) (18.8%). Seven patients underwent robotic anterior resection (RAR) (14.6). A single stapler was fired during each surgery for anastomosis in either of the arms. There were no technical difficulties experienced by the surgeon, no intra operative leak or air leak in powered or manual stapler anastomosis. Table 1 demonstrates the demographic and intraoperative parameters compared in manual and circular staplers. One post operative leak was observed in manual stapler group within 7 days. Three patients required blood transfusion with the ratio of 2:1 (powered: manual). Four patients had complications in our study, amongst them three patients underwent manual anastomosis while one patient underwent powered anastomosis($p<0.24$). One patient required readmission in either of the powered and manual stapler groups respectively. Three patients who underwent powered stapler anastomosis required higher analgesics as compared to none in manual, however it was not statistically significant ($p<0.1$). The mean pain score for patient in powered stapler and manual stapler was 2.96 and 2.92 respectively, while mean length of stay was 7.04 for powered and 6.1 for manual stapler. There was no significant difference between the powered and manual stapler with respect to pain score($p<0.851$) and length of stay ($p<0.08$). 14.8% in PSG (Powered stapler group) underwent diversion ostomy as compared to 14.3% in manual stapler group. Table 2 demonstrates the post operative parameters assessed in powered and manual group of staplers.

Factors	Powered	Manual
Gender Male	19	13
Mean Age	62.25	55.125
Co-morbidities (yes/No)	12/24	16/24
Operating time	200mins, 3.33hrs	200 in mins, 3.33 hrs
Leak test	0	0

Table 1: Demographic and intraoperative parameters in powered and manual stapler groups.

Factors	Powered	Manual	P- value
Post operative leak	0	1	-
Blood transfusion	2	1	>0.1
Re admission	1	1	1
Adverse event	1	3	>0.1
Mean pain score	2.7	2.8	P=<0.851
Length of stay	7.04	6.1	P=<0.08
Use of Higher antibiotics and analgesics	2	0	-

Table 2: Post operative assessment of parameters in the circular powered and manual groups.

Discussion

To our knowledge, this is the first Indian real-world study which compares new generation powered stapler with conventional stapling technology for anastomosis in colorectal surgery. According to Globocan 2020 an estimated number of colorectal cancers in India were 65,358 new cancers every year [13]. The definitive management of colorectal cancer is surgery with colorectal anastomosis being an integral part. Majority of our patients were males and $4/5^{th}$ of patients underwent Laparoscopy/ robotic surgery while $1/5^{th}$ of the patient underwent open surgery. With respect to complication rates an indirect study done by P. S et al comparing the outcomes of powered stapler with historic cohort data of manual circular staplers found statistically significant lower readmission rates 6.1% vs 10%, lower anastomotic leak rates (1.8% vs 6.9%), lower infection (1.8% vs 5.7%) and reduced bleeding (1.8% vs 9.2%) [14]. However, in our study a single post operative leak was observed in manual group. We observed anastomotic leak at post operative day 4 in manual stapler anastomosis showing direct causal relationship. In our study there were no post-operative leaks observed in powered stapler group.

According to a retrospective study done by Patricia Sylla et al anastomotic leak was observed in 1.8%, infection in 1.8%, bleeding in 1.8%, ileus in 4.8% and readmission rate of 6.1% in the powered stapler

group, comparatively in our study 3.7% of patients required readmission, there was no incidence of anastomotic leak, bleeding and bowel obstruction. Incidence of ostomy was 14.8% in our study (Powered Stapler group) PSG as compared to 18.6% in sylla et al study [14]. In this USA study, length of hospital stay was similar in both the PSG cohort and historic cohort group (a vs b). This observation was confirmed even in our study (a vs b). In today's health-care environment length of hospital stay is also influenced by patient expectations, general inefficiency, a lack of postoperative social support, as well as administrative culture [15].

Patients undergoing powered anastomosis received more blood transfusion (2:1) which suggests that patient in the powered stapler group were more co-morbid yet there were no added adverse effects, complication rates including anastomotic leaks, increased length of hospital stay, infection rates or any re-admissions. In our study, only one patient in powered group experienced post op complication such as severe perianal pain requiring readmission. On the contrary, three patients of manual stapler group experienced post operative complications. These complications included post-operative anastomotic leak, wound infection and anastomotic stricture. Patient with anastomotic stricture required re -a admission.

Complication and its management

A patient with carcinoma rectum post radiation therapy (RT) underwent anterior resection using 29 manual circular staplers. Intraoperative no leak was confirmed but patient developed anastomotic leak on post-operative day 4 and was immediately taken up for re-exploration. Intraoperatively, we observed anastomotic leak with pus flakes in the pelvic cavity but no fecal contamination. Peritoneal wash was given and transverse colostomy done. Patient improved and was discharged on post operative day POD 7. It has been shown that preoperative radiation therapy causes vascular and epithelial alterations in the affected tissue, such as capillary bed volume reduction and aberrant mucosal integrity. These changes may lead tissue thickness to deviate from the stapler's recommended range, increasing the risk of anastomotic leakage [16]. However, preoperative treatment distribution was similar in both the groups. Leak was observed only in manual stapling group. Although manual circular staplers are an effective instrument for creating anastomoses, the security and robustness of the seal may be jeopardised due to the inherent difficulties of applying a manual device to sensitive tissue. Manual staplers are known to cause problems with firing and technical errors have remained a challenge with manually fired mechanical circular staplers [17]. Powered stapling devices allow the surgeon to fire the stapler with the push button, reducing the amount of physical force required by the surgeon. This may prevent undesired movement at the distal tip, allowing for a more precise positioning and staple line formation. When compared to manual circular stapling, this device required less force to fire, had less movement during device application, and had less leaking at the staple line in preclinical testing [12]. An initial clinical analysis of 17 left-sided anastomoses performed with the circular powered stapler revealed good safety and anastomotic integrity in all cases right after surgery [18]. In our study we also observed favorable anastomotic results with powered staplers having no anastomotic leak. This could be attributed to differences in physical grip strength, unintentional movement, and level of experience, to create a more technically robust and reproducible anastomosis than is currently possible with manual alternatives.

Another case of carcinoma rectum underwent anterior resection and anastomosis created using 29 powered stapler was readmitted in view of persistent perianal pain on post-operative day 10. However, Computed Tomography (CT) with contrast confirmed no leak and the patient was managed conservatively. There was a readmission of patient with anastomotic non-malignant stricture 3 month post anterior resection with anastomosis done using manual circular 33 stapler. Intraoperative leak test was negative and patient recovered well post operatively, yet he required readmission in view of developing anastomotic stricture and was managed initially by balloon dilation but finally requiring a transverse colostomy. Stricture is a known complication after anastomosis using circular staplers [19]. In our study none of the patients with powered anastomosis developed anastomotic stricture. Study done by Sylla et al found no significant difference in stoma creation, pelvic abscess and length of stay between the two cohorts. Similarly, in our study none of the patient had immediate pelvic abscess in either of the groups. Also, number of stoma creation was similar in both our groups. A prospective questionnaire-based study by Herzig et al analyzing

the experience of powered stapler found abdominal pain as the most common adverse event occurring in 7.1% cases [20]. However, in our study we compared pain score (VAS scale) between the two groups and found comparable. Also, in our study we found trends of higher hospital stay for powered stapler as compared to manual stapler but it was not statistically significant(P<0.8). This observation was similar to that found in Sylla et al group.

All procedures have an inherent risk for complications that is independent of the devices used. It is difficult to ascribe all postoperative complications to the accompanying surgical stapler. Technical errors involving stapler devices do occur, and this calls for surgeons to be vigilant when using these instruments. The vast majority of these are correctable intraoperatively and surgeons need to have a plan in place for when they occur. Additional research is clearly warranted to replicate our results and to investigate the contribution, if any, of pre-existing severe disease (American Society of Anesthesiologists classification), Hinchey classification, and level of anastomosis to technical error.

Limitations

In our study we did not calculate the cost effectiveness of powered staplers, also ease of use, surgeon satisfaction could not be differentiated between the two groups. Further trials are needed to determine the long-term consequences and quality of life in these patients undergoing colorectal anastomosis.

Conclusion

Powered stapling device are safe and efficacious alternative to manual staplers in colorectal anastomosis in real world setting. We observed comparable intraoperative and lower trends of post-operative complication rates in powered staplers' group. Pain score and length of hospital stay were also comparable in powered stapler group. Randomized control trial is needed to confirm the advantage of the powered staplers.

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Name	Role
Dr Tahoora Sarguroh	Manuscript edits

Authors Contributions

Dr. Heroor A has provided the concept and design of work and investigation.
Dr Khatri W has performed the collection and analysis of data and the drafting of manuscript
Dr Nandan A has provided the conception and design of work and investigation.
Dr Meenu M has done the collection and analysis of data
Dr Naidu R has contributed to the collection and analysis of data
Dr Shah H has substantial contribution in the revision of manuscript
Dr Singhavi H has performed the Interpritation and analysis of data as well as contributed in the drafting of manuscript.

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